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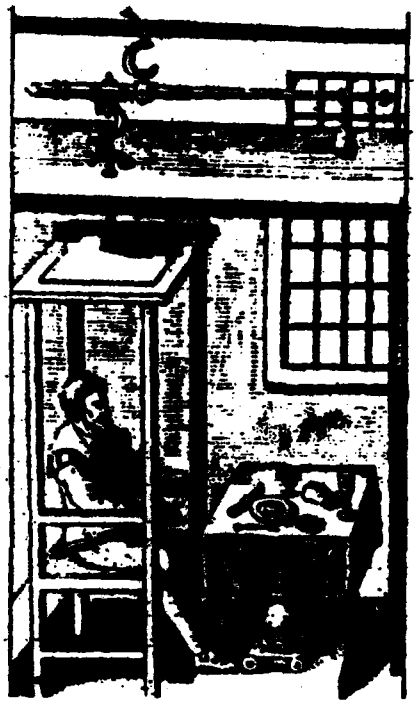
CLINICAL · INVESTIGATION PROGRAM · REPORT



DWIGHT DAVID EISENHOWER

ARMY MEDICAL CENTER
FT. GORDON, GEORGIA 30905

FY · 88

ADA202444

SECURITY CLASSIFICATION OF THIS PAGE (When Data Entered)

REPORT DOCUMENTATION PAGE

READ INSTRUCTIONS BEFORE COMPLETING FORM

1. REPORT NUMBER: RCS MED-300 (R1)	2. GOVT ACCESSION NO.
3. RECIPIENT'S CATALOG NUMBER	
4. TITLE (and Subtitle): Clinical Investigation Program, RCS MED-300 (R1)	5. TYPE OF REPORT & PERIOD COVERED: ANNUAL - FY 88 FINAL
6. PERFORMING ORG. REPORT NUMBER	
7. AUTHOR(s): KENT M. PLOWMAN, M.D., PhD Lieutenant Colonel, Medical Corps Chief, Department of Clinical Investigation	8. CONTRACT OR GRANT NUMBER(s)
9. PERFORMING ORGANIZATION NAME AND ADDRESS: Department of Clinical Investigation Dwith David Eisenhower Army Medical Center Fort Gordon, Georgia 30905-5650	10. PROGRAM ELEMENT, PROJECT, TASK AREA & WORK UNIT NUMBERS
11. CONTROLLING OFFICE NAME AND ADDRESS: Commander Dwight David Eisenhower Army Medical Center Fort Gordon, Georgia 30905-5650	12. REPORT DATE: 31 October 1988 13. NUMBER OF PAGES: 160
14. MONITORING AGENCY NAME & ADDRESS (if different from Controlling Office): Commander US Army Health Care Studies and Clinical Investigation Activity Fort Sam Houston, Texas 78234-6060	15. SECURITY CLASS. (of this report): UNCLASSIFIED 15a. DECLASSIFICATION/DOWNGRADING SCHEDULE

16. DISTRIBUTION STATEMENT (of this Report)

APPROVED FOR PUBLIC RELEASE: DISTRIBUTION UNLIMITED

17. DISTRIBUTION STATEMENT (of the abstract entered in Block 20, if different from Report)

N/A

18. SUPPLEMENTARY NOTES

THE FINDINGS IN THIS REPORT ARE NOT TO BE CONSTRUED AS AN OFFICIAL DEPARTMENT OF THE ARMY POSITION UNLESS SO DESIGNATED BY OTHER AUTHORIZED DOCUMENTS.

19. KEY WORDS (Continue on reverse side if necessary and identify by block number)

Unit Summary; Detail Sheet (Study Objective, Technical Approach, Progress, Status); Publications; Presentations.

> Dentistry, Pathology, Pediatrics, Psychiatry, Neurology, Nursing, Nutrition, Surgery, and Radiology. (AW)

20. ABSTRACT (Continue on reverse side if necessary and identify by block number)

Subject report identifies the research activities conducted by Dwight David Eisenhower Army Medical Center investigators through protocols approved by the Institutional Review Committee for registration with the Department of Clinical Investigation during Fiscal Year 1988, and other known publications and presentations by the Dwight David Eisenhower Army Medical Center professional staff. A detail sheet of each protocol giving the objective, technical approach, and progress is presented. Areas of investigation included

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CLINICAL INVESTIGATION

PROGRAM REPORT

31 October 1988

CONTROL SYMBOL: RCS MED-300 (R1)

Department of Clinical Investigation
Dwight David Eisenhower Army Medical Center
Fort Gordon, Georgia 30905-5650

FOREWORD

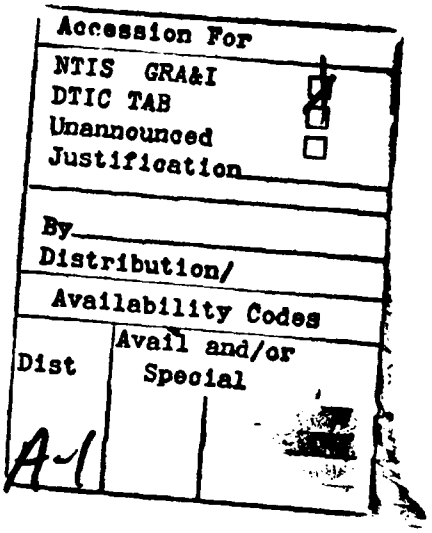
The cover of this year's annual report features a print of the 16-17th century medical school professor, Santorio Santorio (Sanctorius), conducting a pioneering experiment on human metabolism. Seated in his steelyard chair, he would track weight changes occasioned by such activities as eating. His experiments established the concept of "insensible perspiration" and earned him the reputation as the father of metabolism. This work built on the base of the 15th century churchman and physician, Cardinal Cusanus (Nikolaus Krebs of Cues) who suggested the potential clinical thermometer and a pulsilogium for estimating the pulse rate. As so often occurs in new developments, his inventions were neglected for another century. He also invented an instrument for extracting stones from the bladder and foreign bodies from the ear; and is further credited with a trocar, a cannula and a hygroscope.

A contemporary of Sanctorius', the Belgian Capuchin friar turned physician, Jean Baptiste van Helmont, considered metabolism from a more chemical orientation. He recognized the importance of ferments and gases, especially carbon dioxide, which he termed gas sylvestre. He claimed an equivalence with the gas produced by fermentation and combustion, although some confusion with carbon monoxide may have occurred. His knowledge of other physiological processes, including bile and gastric juice, was extensive. He introduced the gravimetric measurement of urine and weighed some 24 hour samples but could draw no important conclusions from his measurements.

Similar frustrations and disappointments accompany the investigative efforts of the modern physician as well. One may work for years on a new means to measure some important variable but be unsuccessful in finding the clinical correlates needed to achieve recognition. Even a relatively apparent measurement, such as blood pressure, has required a remarkably long period of this century to establish the efficacy of pharmacologic control. The case for the control of mild hypertension in the prevention of coronary events or strokes is very recent. The regional distribution of blood flow may be important, but the means to measure it in the right clinical setting is not obvious. Work in progress at DDEAMC is aimed at assessing coronary artery flow restrictions in patients without angina. Such silent ischemia would seem to be of critical prognostic importance since such individuals die at least as frequently as those who have pain. The use of certain ambulatory ECG monitors can detect episodes of ST segment depression which is indicative of ischemia. Prudent adjustment of a patient's medications could minimize the number of such ischemic episodes. Proof of the efficacy of such measures will take years of hard work to assess despite the seemingly self-evident nature.

The new era of physiological measurements is focused on molecular changes at cellular or subcellular interfaces. It is a search for noninvasive, time-critical ways to monitor key events in real time interventions. Infrared imaging has looked at regional blood flow noninvasively to ascertain changes in near surface blood flow under a variety of clinical states with some success here at DDEAMC. Many leading research centers have used positron emission and nuclear magnetic resonance imaging to follow metabolic functions in individual organs during certain physiological states. Such noninvasive measures of in vivo functioning have not yet led to clinical tests of pathological physiology even though they are used for picturing structural changes. To find appropriate new tests of physiological malfunctioning remains one of the goals of the next generation of clinical research as the search turns to molecular events of metabolism and regulation.

We at Eisenhower Army Medical Center are grateful for the support and encouragement of our Commander, BG Frederick N. Bussey, MC, in our continuing effort to achieve new goals in a pursuit of excellence. We acknowledge the support of the deputy commanders, the program directors, the Institutional Review Committee members, the staff and residents, and the Clinical Investigation team effort.



KENT M. PLOWMAN
LTC, MC
Chief, Dept of Clinical Investigation

UNIT SUMMARY - FISCAL YEAR 1988

A. Objective.

The Department of Clinical Investigation is responsible to the Deputy Commander for Clinical Services for providing the facilities and atmosphere of inquiry necessary to support and stimulate both basic and clinical medical investigation within DDEAMC.

B. Technical Approach.

All research, investigational, and training activities within the Department of Clinical Investigation are conducted under the guidance of AR 40-38, AR 40-7, AR 70-25, AR 70-18, and HSC Reg 40-23. Careful monitoring of all approved protocols is conducted in order to assure strict compliance with these applicable regulations.

C. Staffing.

Name	Rank	MOS	Title
Plowman, Kent M.	LTC	61F00	Chief
Hofmann John R.	MAJ	64F00	Veterinarian
Sutherland, Donald E.	MAJ	68C00	Biochemist
Paustian, Paul W, Jr.	MAJ	60E00	Research Surgeon
Turgeon, David K.	CPT	68A9B	Immunologist/Microbiologist
Nead, Charles L.	SGT	92B20	NCOIC, Med Lab Sp
Decker, Rodney	SGT	92B20	Med Lab Sp
Morris, Kathy	SGT	92B20	Med Lab Sp
McCullers, Manuela	SGT	91T10	Animal Sp
Ellis, Saundra	PFC	91T10	Animal Sp
Horner, Jack A.	GM13	01301	Asst C, S. Res Histologist
McPherson, James C. III, PhD	GS12	01320	Biochemist
Runner, Royce R.	GS11	00644	Medical Technologist
Martinez, Rosina	GS7	00303	Protocol Coordinator
Burnette, Jane A.	GS4	00312	Clerk-Steno
Hinton, Alma*	GS7	00404	Biological Lab Technician
Zadinsky, James**	GS7	01531	Statistics Asst (Temp 1 yr)
Challenger, Patricia	GS11	00644	Study Coordinator (5-yr term Dermatology Svc, NIH Grant)

*Detailed to Cardiology
**Terminated Apr 88

D. Funding.

Type	Fiscal Year 87	Fiscal Year 88
Civilian personnel to include benefits	219,828.00	215,899.00
Consumable supplies	77,388.00	84,710.00
Civilian contracts to include consultants	4,212.00	4,847.00
TDY*	10,083.00	11,100.00
Publications	2,909.00	7,086.00
Noninvestment equipment (Minor MEDCASE)		
OMA Total	314,370.00	312,542.00
MEDCASE	270,198.00	99,375.00
Military	394,262.00	483,312.00
Total	978,830,00	895,229.00

*Includes Clinical Investigation personnel plus other paper presentations from Dwight David Eisenhower Army Medical Center staff and residents.

E. Progress.

Protocol Disposition FY 88

	Completed	Terminated	Ongoing to FY 88
FY 78	-	-	2
FY 79	-	-	-
FY 80	-	-	-
FY 81	-	1	-
FY 82	-	-	-
FY 83	-	-	3
FY 84	-	1	5
FY 85	-	-	3
FY 86	4	1	1
FY 87	20	4	17
FY 88	3	2	30
	27	9	61

In addition to the above totals, three studies were transferred to WRAMC.

INSTITUTIONAL REVIEW COMMITTEE

Clinical Investigation and Human Use Members

Chief, Department of Clinical Investigation, Chairman
Chief, Department of Medicine
Chief, Department of Surgery
Chief, Pharmacy Service
Research Director, Dental Activity
Chief, Department of Ministry & Pastoral Care
Chief, Nursing Education & Staff Development
Signal Center Representative, Ft Gordon, Georgia
Chief, Department of Pathology
Research Director, Department of Family Practice
Research Director, Department of Psychiatry & Neurology
Medical Center Judge Advocate
Chief, Nuclear Medicine Service
Chief, Medical Records Administration Section

Animal Use Members

Chief, Department of Clinical Investigation, Chairman
Chief, Department of Medicine
Chief, Department of Surgery
Veterinarian, Department of Clinical Investigation
Signal Center Representative, Ft Gordon, Georgia

RESEARCH AWARDS

Recipient of

The Sixth Annual DDEAMC Resident Reseach Award
was

Major Donald W. Grogan, MC, a Child Psychiatry Fellow
for his paper

"The Ability of Mothers to Recognize Their Infants by Smell: The Implications for Parent-Child Bonding"

The paper based on Protocol #87-50 was presented at the American Psychiatry Association Meeting in Montreal, Canada in May 1988, and at the Menninger Memorial Conference Armed Forces Psychiatry Course in Topeka, KS in April 1988.

Recipient of

The Second Annual Dental Activity Resident Research Award
was

Major Murray J.A. Cuff, DC, a Periodontal Resident
for his paper

"The Presence of Nicotine on Root Surfaces of Periodontally Diseased Teeth in Smokers"

The paper based on Protocol #87-20 was presented at the Society Armed Forces Medical Laboratory Sciences in Reno, NV in March 1988. The manuscript has been submitted to the Journal of Periodontology.

TABLE OF CONTENTS

* * * * *

Code:

O - Ongoing
C - Completed
W - Withdrawn
T - Terminated
TR - Transferred

P - Published
PR - Presented

PUBLICATIONS FY 88

DEPUTY COMMANDER FOR CLINICAL SERVICES

Manning DT, Xenakis SN: Prevalence of Type A behavior in American combat soldiers and their children. Mil Med 1988; 153(7):358.

Jensen PS, Traylor J, Xenakis SN, Davis H: Child psychopathology rating scales and interrater agreement: I. Parents' gender and psychiatric symptoms. J Am Acad Child Adolesc Psychiatry 1988; 27(4):442-450.

Jensen PS, Xenakis SN, Davis H, DeGroot J: Child psychopathology rating scales and interrater agreement: II. Child and family characteristics. J Am Acad Child Adolesc Psychiatry 1988; 27(4):451-461.

Jensen PS, Grogan DG, Xenakis SN, Bain MW: Father absence: Effects on child and maternal psychopathology. (Abstract) Proc Am Psychiatric Assn, 1988; p. 69.

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Jensen PS, Xenakis SN, Shervette RS, Bain M: Medical and psychosocial histories in children treated for attention deficit disorder. J Am Acad Child Adolesc Psychiatry. (In Press)

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DEPARTMENT OF CLINICAL INVESTIGATION

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Nead CL, McPherson JC III, Ward DF, McPherson JC Jr: Effect of tetramethylammonium chloride on the red cell membrane. (Abstract) Am Chem Soc, Southeast Region 1987; 39:55. (C)

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Runner RR, McPherson JC III, Ward DF, McPherson JC Jr: Vitamin D deficiency in adult male rats: Changes in red cell deformability. (Abstract) Soc Experi Biology Med, Southeast Section 1987: 12:19. (C)

Nead CL, McPherson JC III, Ward DF, McPherson JC Jr: Osmotic and mechanical fragilities of red blood cells from vitamin D deficient adult rats. (Abstract) Soc Experi Biology Med, Southeast Section 1987: 12:19. (C)

Buxton TB, Horner J, Hinton A, Rissing JP: In vivo glycocalyx expression by staphylococcus aureus phage type 52/52A/80 in S. aureus osteomyelitis. J Infec Dis 1987; 156(6):942-946.

Rissing JP, Buxton TB, Horner JA, et al: Synergism between bacteroides fragilis and staphylococcus aureus in experimental tibial osteomyelitis. J Lab Clin Med 1987; 110(4):433-438.

McPherson JC Jr, Kirby SG, Ward DF, McPherson JC III: Failure of different dietary fats to alter the effects of hypervitaminosis D on food intake and body weight. (Abstract) Georgia J Sci 1988; 46(1):61. (C)

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Guy SC, McQuade MJ, Scheidt MJ, Rossmann JA, McPherson JC III, Van Dyke TE: In vitro attachment of human gingival fibroblasts to fibronectin-treated and non-treated endosseous implant materials. Submitted to J Periodontol. (C)

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Grover PS, McPherson JC III, McQuade MJ, Rossmann JA, Schuster GS, Van Dyke TE: Initial attachment of fibroblast to bone graft materials in vitro. Submitted to J Periodontol. (C)

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Sutherland DE, Schumm DE: High performance gel permeation studies of a 6-kilodalton oncofetal tumor marker. (Abstract) Clin Chem 1988; 34:1299.

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Burke MH, McQuade MJ, Scheidt MJ, Rossmann JA, McPherson JC III: Endotoxin removal from tooth root surface by brushing. (Abstract) Georgia J Sci 1988; 46(1):44. (C)

Emert RL, McQuade MJ, Scheidt MJ, McPherson JC III: Identification of attachment sites of human fibroblasts using sulfhydryl blocking agents. (Abstract) Georgia J Sci 1988; 46(1):49. (C)

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Guy SC, McQuade MJ, Scheidt MJ, Rossmann JA, McPherson JC III, Van Dyke TE: In vitro attachment of human gingival fibroblasts to fibronectin-treated and non-treated endosseous implant materials. Submitted to J Periodontol. (C)

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Grover PS, McPherson JC III, McQuade MJ, Rossmann JA, Schuster GS, Van Dyke TE: Initial attachment of fibroblast to bone graft materials in vitro. Submitted to J Periodontol. (C)

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Kucera RF, et al: Brain pH effects of $NaHCO_3$ and carbicarb in lactic acidosis. Submitted to J Crit Care Med.

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DEPARTMENT OF NURSING

Allanach BC: Interviewing to evaluate preceptorship relationships. Submitted to J Nurs Staff Dev.

DEPARTMENT OF PATHOLOGY

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Caldwell CM, Watson CV, Townsend GG: Pitfalls in therapeutic drug monitoring. Part I. Salicylates. Submitted Lab Med.

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Sen JK: Hypoplastic acute myelogenous leukemia. Submitted Am J Clin Pathology.

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Zadinski JK, Broome ME: Clinical nursing research: You can do it. Accepted J Pediatric Health Care.

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Jensen PS, Grogan DG, Xenakis SN, Bain MW: Father absence: Effects on child and maternal psychopathology. (Abstract) Proc Am Psychiatric Assn, 1988; p. 69.

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Code:
(C) - Results of clinical study

PRESENTATIONS FY 88

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DEPARTMENT OF CLINICAL INVESTIGATION

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McQuade MJ: Periodontics for the general practice resident. Ft Benning, GA, 5-6 Nov 1987.

Scheidt MJ: The role of the peridontist in TMJ therapy. Teaching Chiefs Conf, Ft Sam Houston, San Antonio, TX, 11-14 Jan 1988.

McQuade MJ: The modified widman flap history and technique. Short Course in Periodontics. 8-11 Feb 1988.

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DEPARTMENT OF MEDICINE

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McNally PR, Maydonovitch CL, Wong RKH: The effectiveness of simethicone in improving visibility during colonoscopy: A double blind randomized study. 16th Ann William Beaumont Gastrointestinal Symposium, San Francisco, CA, Oct 1987.

Mecredy T: A case of signet ring cell adenocarcinoma of the rectum. ACP, San Francisco, CA, Oct 1987.

Cook JR: Faculty member: Basic Cutaneous Surgery-Soft Tissue Workshop, Medical College of Georgia, 4-5 Jun 1988.

Guill MA: Chronic bullous disease of childhood. Clinicopathologic Conf Tri-Services Mtg, Bandera, TX, May 1988.

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DEPARTMENT OF NURSING

Allanach BC: Transition into military nursing: Evaluating the effects of a nurse preceptorship program. Phyllis J. Verhonick Nursing Research Course, Chevy Chase, MD, 11-15 Apr 1988.

DEPARTMENT OF PATHOLOGY

Townsend GG, Watson CV: Applied practical therapeutic drug monitoring with case studies. Am Soc Med Technology Region III and Am Med Techologist Southern District Mtg, Savannah, GA, 13-16 Oct 1987.

Sen JK: Immunoblastic sarcoma, T-cell type. Regional Soc Pathologists, Augusta, GA, 29 Oct 1987.

Monihan JM: Alveolar soft part sarcoma. Regional Society Pathologists, Ft LGordon, BA, 3 Mar 1988.

Sen JK: Hodgkins disease: Past, present, and future. Invited Lecture, Research Society, Department of Pathology, MCG, Augusta, GA, 3 Mar 1988.

Sen JK: Leukemia cytochemistry. Invited lecture, School of Medical Technology, MCG, Augusta, GA, 2 Mah 1988.

Fincher EW: The yellow IRIS automated urinalysis. Technological Advances in Medical Technology Symposium, MCG, Augusta, GA, 6 May 1988.

Watson CV: New developments in physician office testing equipment. Advances in Office Lab Medicine Symposium, DDEAMC, Ft Gordon, GA, 27 May 1988.

Wagstaff BB: Metastatic cytosarcoma phylloides. Augusta Regional Society Pathologists, Augusta, GA, 2 Jun 1988.

Watson CV: Therapeutic drug monitoring. Instructional videotape, DDEAMC Audio Visual Department, 1988.

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DEPARTMENT OF PEDIATRICS

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Francis GL, Zadinsky J, Heffman W, Gala R: Evidence suggesting fetal control of neonatal breast development. Uniformed Soc Am Acad Peds, San Diego, CA, Mar 1988. (C)

DEPARTMENT OF PRIMARY CARE

Gilman PA: Pulmonary hemosiderosis. Columbus Medical Center, Columbus, GA, 3 Mar 1988

Gilman PA: Evaluation of anemia in infants. Teaching Conference, Columbus, GA 3 Mar 1988.

DEPARTMENT OF PSYCHIATRY AND NEUROLOGY

Jensen PS, Shervette RL, Xenakis SN: Anxiety and depressive disorders in ADD: New findings. Am Psychiatry Assn, Montreal, Canada, 7-12 May 1988. (C)

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Jensen PS, Josephson AM, Frey J: Informed consent: Legal content vs therapeutic process. Am Psychiatry Assn, Montreal, Canada, 7-12 May 1988.

Jensen PS, Ness R, Wolf PL: Multidisciplinary research teams: A model for 1990's. Am Psychiatry Assn, Montreal, Canada, 7-12 May 1988.

Jensen PS, DeGroot J: Explanatory models of A.D.D. present status future directions. Am Psychiatry Assn, Montreal, Canada, 7-12 May 1988. (C)

DeGroot J: Concept of self in ADD: An application of piaget and protective testing. Am Psychiatry Assn, Montreal, Canada, 7-12 May 1988. (C)

Jensen PS, Hendricks D, Ness R, Jensen JW: Alcoholism treatment outcomes: Effects of pre-treatment stresses and social supports. Am Psychologic Assn, Atlanta, GA, Aug 1988. (C)

Nolan WP, Jensen PS, Hendricks D, Hester TW: Alcohol treatment outcome: Abstinence in a structured military environment. Am Psychologic Assn, Atlanta, GA, Aug 1988. (C)

Bloedau LJ, DeGroot JF, Jensen PS: Children at risk: Psychopathology correlates in clinical and community samples. Am Psychologic Assn, Atlanta, GA, Aug 1988.

Pichot JT: The potential role of psychiatry residents councils. Georgia Psychiatric Assn, Atlanta, GA, 5-7 Feb 1988. Dr. Pichot was awarded the Hope Skobba Resident Award for this paper.

Tanz FJ: Psychiatric aspects of AIDS. Regional Symposium, DDEAMC, Ft Gordon, GA, 26 Feb 1988.

Hendricks D: Sheehan TD, Jensen PS, Jensen J, Hester T, Nolan W, Ness R: Alcohol inpatient treatment outcomes. Am Psychologic Assn, Atlanta, GA, 12-16 Aug 1988. (C)

Hendricks D, Sheehan TD, Jensen PS, Jensen J: Research as an integral part of chemical addiction treatment. Medical College of Georgia, Augusta, GA, 27 Apr 1988. (C)

Grogan D: The ability of mothers to recognize their infants by smell: Implications for parent-child bonding. Menninger Memorial Conference/Armed Forces Psychiatry Course, Topeka, KS, Apr 1988. (C)

DEPARTMENT OF SURGERY

Anesthesiology & Operative Service

Brookshire GL: Sympathetic blockade versus adenosine monophosphate for the prevention and treatment of postherpetic neuralgia. Am Soc Anesthesiologists, Atlanta, GA, 14 Oct 1987. (C)

Ophthalmology Service

Moses KC: The management of pterygium. Ophthalmology Biannual Alumni Mtg, Washington, DC, 19 Mar 1988.

Orthopedic Service

Montijo H, Barja RH: Cubital tunnel syndrome. Annual Meeting Soc Experimental Biology & Medicine, SE Section, Augusta, GA 12-14 Nov 1987.

Drakeford MK: Diagnosis of rotator cuff disease. Annual Meeting Soc Experimental Biology & Medicine, SE Section, Augusta, GA, 12-14 Nov 1987. (C)

Barja RH: Hand pathology IQ. Am Acad Orthop Surgeons Annual Meeting, Atlanta, GA, 4-9 Feb 1988.

Anderson RC: Complications of intramedullary fixation of the femur. Orthop Rev Crs, Philadelphia, PA, 2-9 Apr 1988.

Drakeford MK, Quinn MJ, Simpson SL, Pettine KA: A comparative study of ultrasonography in evaluation of the rotator cuff. Am Orthop Assn Residents Conf, Boston, MA, 16-19 Mar 1988. (C)

Montijo H, Barja RH: Anterior ulnar transposition - Comparison between submuscular and subcutaneous transposition. SOMOS, San Diego, CA, Nov 1987.

Tidwell MA: Revision of failed posterior spinal instrumentation using Cotrel-Dubousset instrumentation. 5th Int Congress Cotrel-Dubousset Instrumentation, Paris, France, 21-25 Jun 1988.

Simpson SL, Barja RH: Ultrasound evaluation of the plantaris tendon. Ann Residents and Fellows Mtg Am Soc Surg Hand, Baltimore, MD, Sep 1988.

Tidwell MA: Introduction to Cotrel-Dubousset. Florida Orthop Soc, Lake Buena Vista, FL, 19-21 Nov 1987. 16th Ann Symposium Children's Orthop, FAMC, Aurora, CO, 9-11 Mar 1988.

Code:
(C) Results of clinical study

MARTIN ARMY COMMUNITY HOSPITAL
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McGlaughlin VG: Core seeking behavior after a mass casualty event. USAFP Convention, Mar 1988.

McGlaughlin VG: Lung abscesses in children. USAFP Convention Apr 1988.

Smith D: Pulmonary embolis - Controversies in management. USAFP Convention, Apr 1988.

Alverio CE: The role of occupational therapists in a natural disaster. Occupational Therapists Active Duty, Reservises and National Guard, Las Vegas, NV, 12 Nov 1987.

Baker GD: Reporting adverse drug reactions. Ralph D. Arnold Pharmaceutical Management Conf, San Antonio, TX, 10 May 1988.

Reynolds PF: In vitro fertilization: Standing in line for miracles. Tri Service Armed Forces District NAACOG Mtg, Cherry Point, NC, May 1988.

Cardinal PA: Small group patient education. Ann Conf Patient Education Primary Care Setting, Kansas City, MO, 15-17 Sep 1988.

Steinbook MN: Ogilvie's syndrome: Medical versus surgical intervention. A review of 34 cases. Am Coll Physicians, San Francisco, CA, Oct 1987.

Graham JI: Pregnant women in the workforce. Mil District NAACOG Ann Conf, Marine Air Station, Cherry Point, NC, 7 May 1988.

Graham JI: Maternal employment and perinatal outcome. NAACOG Columbus/Ft Benning Chapter, 23 Jun 1988.

Boucher RL: Effective use of computers in nursing. Georgia Nurses Assn Psychiatric Council, Macon, GA, 19 Mar 1988.

Koehler WT: Psychopharmacology for psychiatric nursing. Columbus College, Columbus, GA, 13 May 1988.

Koehler WT: Registered care technologists - An issue for nursing. Georgia Nurses Assn, District 3, Columbus, GA, 28 Jul 1988.

Rivera J: Ethrohealth and ethrocare: A study of elderly Italian (Tuscan) Americans. 10th Ann Transcultural Care Conf, Boca Raton, FL, 8-13 May 1988.

DETAIL SUMMARY SHEETS

Detail Summary Sheet

Date: 12 Oct 88 Prot No.: 84-50		Status: Ongoing
Title: A Scanning and Transmission Electron Microscopic Study of the Effects of Cadmium on the Early Developmental Components of the Craniofacial Region of the Hamster Embryo		
Start Date: Jul 84		Est Comp Date: Dec 89
Principal Investigator(s) Jack A. Horner, B.S. Thomas F. Gale, PhD		Facility: Eisenhower Army Medical Center Medical College of Georgia
Dept/Svc: Clinical Investigation Anatomy Dept, MCG		Associate Investigators:
Key Words: Electron microscopy, Cadmium, Teratology		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Sep 88 Results Continue

Study Objective: To utilize electron microscopy to compare the fine structural features of the component tissues of 13 different regions of the face at selected timed-intervals during the early development of the craniofacial region in cadmium-exposed vs control hamster embryos.

Technial Approach: Cadmium sulfate solution is injected (IV) into timed pregnant golden hamsters on the eighth gestation day (8 AM) and embryos are collected at selected times during the period of early facial development, i.e., day 8 at 6PM; day 9 at 8AM; day 10 at 8 AM; day 10 at 6PM; day 11 at 8 AM. The embryos are fixed, dehydrated by critical point drying, coated with gold, and examined and photographed in the scanning electron microscope. Comparisons between embryos from the control (sham-injected) and experimental (cadmium-injected) pregnant hamsters will reveal the teratogenic effects of cadmium on the developing embryonic face. The comparisons will be both qualitative and quantitative. Collection of the quantitative data on surface area measurements will be accomplished by utilization of a computer interfaced morphometric digitometer system.

Progress: Work is continuing on the TEM/x-ray spectrometric localization of cadmium at the subcellular level and preliminary results are encouraging. The embryos used in the completed frontal view studies (results published are being re-examined in profile to determine the extent of lateral alterations. These results will be correlated with the published data.

Gale TF, Horner JA: The effect of cadmium on the development of the facial prominences: Surface area measurements of day 10 - 8 A.M. hamster embryos. Teratology 198; 36:379-387.

Detail Summary Sheet

Date: 26 Sep 88 Prot No.: 86-28		Status: Completed
Title: Computer Assisted Infrared Imaging in the Diagnosis and Management of Military Basic Training Injuries.		
Start Date: May 87		Est Comp Date: Nov 87
Principal Investigator(s) Margarete DiBenedetto, MD, COL MC		Facility: USAMEDDAC, Ft Jackson, SC
Dept/Svc: Physical Medicine		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To determine possible utilization of thermography in the diagnosis and treatment of injuries received during military basic training.

Technical Approach: Basic trainees were imaged with infrared scanning before training and every two weeks thereafter. Six positions were utilized to thermographically examine the lower extremities.

Number of subjects enrolled to date: 100
Number of subjects enrolled for reporting period: 0

Progress: The experimental part of the study was completed. Analysis of the data showed correlation with clinical signs and symptoms in some areas and lack of correlation in others. The greatest difficulty experienced was the totally inadequate processing of photos, which made evaluation of findings almost impossible after the loaned equipment was returned to the company. While the information is still on floppy discs, I have no access to view them. Therefore, interpretation is mainly from immediate observations and notes. Fortunately, we took several areas in all the foot thermograms and recorded the temperatures systematically from the floppy discs. Another aspect of considerable concern is the inability to correlate objective findings with clinical observations in the health clinics. The medical chart of each study subject was clearly identified, a hard card was placed on the front of the record, on which the examining and treating health care provider was requested to note date, diagnosis and treatment. Unfortunately, this request was not heeded and the clinical information is sparse. This forced me to use, as the only correlation, the questionnaires completed by the study subjects each time they were seen, and my own remarks noted by obvious clinical observations. In spite of these shortcomings certain statements can be made:

1. Stress fractures indeed can be identified with thermography and progress of healing observed.

2. Reflex sympathetic dystrophy can be recognized, the value of which is especially significant, when not suspected clinically. An example was a

soldier who had an ankle sprain. He developed a widespread area of "reflex" cooling especially proximal to his injury site. It is of interest to note that he got a blister shortly thereafter and rapidly developed a significant infection, which had to be treated aggressively with IV antibiotics and one week hospitalization.

3. The extension of infection can easily be recognized on the thermogram.

4. It is strongly suggestive that the thermographic pattern of the foot can identify the "decompensated flat foot" (inflammatory process secondary to overuse) and differentiate it from the "compensated flat foot" which shows a perfectly normal thermogram.

5. Plotting a graph of the number of abnormalities observed in a specific time frame, it can be noted, that there are definite peaks observed during the third and fifth week. This correlates with the clinical observation of peak injury incidence.

6. Comparing the graphs demonstrating incidence of objective abnormalities observed with graphs depicting numbers of subjective complaints, it can be noted, that objective changes are more frequent than clinical complaints. The curves of the male soldiers mostly show similar configurations, while the graphs demonstrating the incidence of complaints vs objective changes of the female soldiers show a number of discrepancies.

Since this was only a pilot study, and especially considering the above mentioned deficiencies, further investigations are necessary and recommended.

Detail Summary Sheet

Date: 7 Oct 88 Prot No.: 87-16		Status: Ongoing
Title: Utility of the 60-Kilodalton Oncofetal Tumor Marker in the Effectiveness of Surgical Intervention in the Treatment of Cancer Patients.		
Start Date:		Est Comp Date:
Principal Investigator(s) Donald E. Sutherland, MAJ, MS		Facility: Eisenhower Army Medical Center
Dept/Svc: Clinical Investigation, Surgery		Associate Investigators: Paul W. Paustian, MD, MAJ, MC
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Mar 88 Review Results Continue

Study Objective: To determine if the 60-kilodalton tumor marker is effective in monitoring the tumor status of patients with various types of cancer by determination of its activity post-surgery.

Technical Approach: Patients undergoing surgery for colon, breast, and lung cancer, and melanoma will have plasma drawn prior to surgery and 48 and 72 hours after surgery. The 60-kilodalton oncofetal tumor marker will be determined in all specimens and compared with results obtained in healthy volunteers. If possible, cancer patients will have plasma drawn and assays run on followup examinations, three to six months after surgery.

Total number of subjects enrolled to date: 12
Total number of subjects enrolled for reporting period: 0

Progress: Problems involved with nuclear lysis during the incubation stage of the 60-kilodalton tumor marker assay may have been solved with the serendipitous discovery of a nuclear stabilization factor in human plasma, which may be able to substitute for the stabilization factor historically obtained from rat liver cytosol, which is expensive and time-consuming to prepare, and has often not been suitable in the past. Preliminary tests with nuclear stabilization factor from whole or ammonium sulfate fractionated plasma have been encouraging. The discovery of the nuclear stabilization factor has important implications of its own, as it had been assumed to be a constituent of rat liver cytosol, but had never been isolated, nor had its presence been demonstrated in plasma. Further study of this factor itself is warranted.

Detail Summary Sheet

Date: 4 Oct 88	Prot No.: 87-17	Status: Ongoing

Title: Red Cell Protection in Major Third Degree Burns in Guinea Pigs.

Start Date: Feb 88		Est Comp Date: Feb 89
Principal Investigator(s) Paul W. Paustian, MD, MAJ, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Clinical Investigation		Associate Investigators: James C. McPherson III, PhD Randall R. Haase, MD, CPT, MC
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Sep 88 Review Results Continue

Study Objective: To analyze in an animal model the protective effect of surfactants in preventing hemolysis and erythrocyte cell membrane damage following exposure of the subject to a 50-80% burn surface area. To correlate any beneficial effect with an optimum plasma concentration of the surfactant.

Technical Approach: The established method of Adams et al (Circ Shock 1981; 8:613) will be used. Serial blood samples will be drawn 1 hour post burn and at six hour intervals through 36 hours and analyzed for hematocrit, hemolysis, red blood cell fragility and elasticity. Six groups of animals will represent: 1) control - sham, 2) control - without blood drawn, 3) surfactant IV, 30 min post burn, 4) surfactant IV, 60 min post burn, 5) surfactant IV 90 min post burn, and 6) surfactant IV immediately prior to burn.

Progress: Since the onset of this study four surfactants (F68, F88, F127, F108) have been examined. As an economy measure the laboratory animal has been changed from guinea pig to rat. All compounds tested have improved the resiliency of red cells in a major burn environment to osmotic and mechanical fragility. Mechanical deformability has also been decreased in the majority of cases. Blood flow rates through the skin vasculature have been studied in unburned animals with three of the compounds to date (F68, F108, F127). Decreased inflammatory reactions in burn wounds have been noted subjectively with several of these compounds. Oxygen diffusing effects experiments are in their preliminary stages at the time of this writing.

Detail Summary Sheet

Date: 12 Oct 88	Prot No.: 87-40	Status: Ongoing

Title: Pathology Applications of X-ray Spectrometric Microanalysis.

Start Date:		Est Comp Date: Dec 89
Principal Investigator(s) Jack A. Horner, B.S.		Facility: Eisenhower Army Medical Center
Dept/Svc: Clinical Investigation/Pathology		Associate Investigators: Phyllis Brewer
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To utilize specimens obtained during routine surgical and autopsy pathology examinations to gain expertise in applications of x-ray spectrometric microanalysis.

Technical Approach: Tissue specimens without known abnormalities of elemental composition are selected from the daily laboratory workload. These are examined for establishment of baseline spectrometric spectra following the use of various fixatives. These spectra can then be compared against specimens with known or suspected elemental abnormalities.

Manpower demands have been met by the principal and associate investigators alone.

Funding has not required the allocation of any additional funds.

Progress: The number of reference samples has approximately doubled during the past year. The scope of this study has been expanded to include electron energy loss spectroscopy. The reason for this is the superiority of this method for the detection of light elements. An expanded data base is being accumulated to accomodate these changes.

Detail Summary Sheet

Date: 1 Jul 88 Prot No.: 87-18		Status: Completed
Title: Comparison of Four Surgical Root Planing Approaches to Endotoxin Removal.		
Start Date: Jan 87		Est Comp Date: Jun 88
Principal Investigator(s) Mary H. Burke, MAJ, DC		Facility: Tingay Dental Clinic, DDEAMC
Dept/Svc: Dental Activity		Associate Investigators: Jeffrey Rossman, COL, MC Michael J. Scheidt, COL, MC
Key Words: Root planing; Endotoxin removal		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To evaluate and compare the quantity of bacterial endotoxin remaining on root surfaces following four instrumentation procedures: Tooth brushing, hand curettes; use of a Cavitron ultrasonic scaler; and use of an air-powder abrasive system, the Prophy Jet.

Technical Approach: Forty extracted teeth were sectioned longitudinally with one half of the root serving as a control and the other half treated with one of four different methods stated above. Crowns were removed and the root halves subjected to Westphal and Jann's pheno/water extraction procedure for endotoxin removal. The endotoxin extract was reconstituted in 2 ml of pyrogen-free water and assayed, using a chromogenic Limulus Amebocyte Lysate Assay. The root halves were weighed and EU were expressed as EU/g of root. Control and treated halves were compared as well as treated halves, using student's t-test.

Progress: Results showed all four methods of root preparation to significantly reduce endotoxin levels. There was no significant difference between tooth-brushing and use of the Cavitron in endotoxin removal. Toothbrushing and the Cavitron were found to be significantly less effective than both the hand curette and Prophy Jet. The Prophy Jet was as effective or better than the hand curette in removing endotoxin.

Detail Summary Sheet

Date: 3 Oct 88	Prot No.: 87-19	Status: Completed

Title: Identification of Attachment Sites of Human Fibroblasts.

Start Date:		Est Comp Date:
Principal Investigator(s) Richard L. Emert, MAJ, DC		Facility: Tingay Dental Clinic, DDEAMC
Dept/Svc: Dental Activity/Clinical Investigation		Associate Investigators: James C. McPherson III, PhD Jack A. Horner Michael J. McQuade, COL, DC Michael J. Schiedt, COL, DC
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To study the mechanism of attachment of fibroblasts and "map" fibroblast sites of attachment using electron microscopy and x-ray energy spectroscopy analysis.

Technical Approach: Incubate cultured fibroblasts (human gingival) at various times. At these various times (0-300 minutes), add sulfhydryl binding reagents (both standard and fluorescent) to fibroblasts. Sulfhydryl binding reagent will supposedly bind the proteins at the attachment sites. Then, map the sites using SEM, x-ray spectroscopy, and fluorescence.

Progress: A monolayer of human gingival fibroblasts were separated into individual cells by trypsination, suspended in RPMI growth media and placed in individual culture flasks for various time periods. At the completion of the time allowed for attachment, a fluorescent sulfhydryl specific binding agent was added. Cells were visualized by fluorescent light microscopy. The cell surface exhibited a uniform flourescence indicating sulfhydryl groups in the cell surface membrane. Bright fluorescent spots indicating possible specific attachment sites were visualized. Groups of cells exhibited multiple fluorescent spots. This data lends support to the theory that fibroblasts attach to the substrate via specific attachment sites probabily associated with specific morphologic structures such as filopodia.

Detail Summary Sheet

Date: 2 Jun 88 Prot No.: 87-20		Status: Completed
Title: The Presence of Nicotine on Roots of Periodontally Diseased Teeth in Smokers.		
Start Date: Jul 86		Est Comp Date: Jun 88
Principal Investigator(s) Murray J.A. Cuff, CPT, DC		Facility: Tingay Dental Clinic, DDEAMC
Dept/Svc: Dental Activity/Clinical Investigation		Associate Investigators: Michael J. McQuade, COL, DC Michael J. Scheidt, COL, DC Donald Sutherland, MAJ, MS
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To determine the presence of nicotine on the roots of periodontally diseased teeth in smokers at the supragingival, periodontal pocket and attached root levels.

Technical Approach: Extract nicotine from 15-20 previously extracted periodontally diseased smokers' teeth. Quantitative analysis will be performed and reported as mass of nicotine per mass (or surface area) of tooth root at the supragingival, periodontal pocket and attached levels.

Progress: Twenty-nine extracted, single-rooted teeth from 11 smokers were brushed clean, and the roots sectioned longitudinally. The respective halves were either left untreated (Group A) or thoroughly root planed (Group B). Pulpal tissue was removed and the individual root sections were weighed. Each half was extracted for nicotine using a methylene chloride technique. Quantification was performed using high pressure liquid chromatography and the sections compared on a nicotine per root weight basis. Results showed a greater amount of nicotine present on non-root planed sections than on treated sections, although some treated specimens revealed small amounts of the substance. This suggests that nicotine is present on the root surface but is removed by thorough root planing. This is not surprising in light of the recent finding that nicotine and cotinine, the major metabolite of nicotine, is found in gingival crevicular fluid. Recent studies have shown a particularly harmful effect of nicotine on fibroblasts. Its presence on root surfaces may therefore impair wound healing and alter the host response in periodontal disease. The use of tobacco products in conjunction with periodontal therapy may interfere with optimal healing.

Detail Summary Sheet

Date: 2 Jun 88	Prot No.: 87-21	Status: Completed

Title: In Vitro Fibroblast Attachment to Fibronectin-Treated Synthetic Implant Materials.

Start Date: Feb 87		Est Comp Date: May 88
Principal Investigator(s) Steven C. Guy, MAJ, DC		Facility: Tingay Dental Clinic, DDEAMC
Dept/Svc: Dental Activity/Clinical Investigation		Associate Investigators: Jeffrey A. Rossman, COL, DC Michael J. McQuade, COL, DC James C. McPherson III, PhD
Key Words: Fibronectin, Implant, Hydroxylapatite, Fibroblast, Titanium		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To determine if fibronectin increases the attachment of fibroblasts to synthetic implant material (hydroxylapatite and tricalcium phosphate).

Technical Approach: Fibroblast attachment and adhesion to titanium, porous hydroxylapatite, and non-porous hydroxylapatite will be quantified using radioactively tagged gingival fibroblasts. Attachment and adhesion will be measured using fibronectin-treated implant materials and non-treated implant materials.

Progress: There was no significant difference in fibroblast attachment when test samples which had been treated with fibronectin were compared to controls. Fibronectin did not appear to increase the number of cells which attached to the various materials. Though fibronectin did not appear to influence fibroblast attachment, the nature of the material itself appeared to influence the number of cells which attached. Fibroblast attachment was greatest to non-porous HA, followed by titanium. Porous HA demonstrated the least amount of fibroblast attachment, presumably because of the far greater surface area involved. Results suggest that that surface geometry of the various synthetic implant materials may influence fibroblast attachment in vitro.

Detail Summary Sheet

Date: 2 Jun 88 Prot No.: 87-23		Status: Completed
Title: Comparison of an Experimental Approach to Closed Root Planing With a Conventional Approach.		
Start Date: Jan 87		Est Comp Date: Jun 88
Principal Investigator(s) Emanuel J. Hnarakis, LTC, DC		Facility: Tingay Dental Clinic, DDEAMC
Dept/Svc: Dental Activity		Associate Investigators: Jeffrey A. Rossman, COL, DC Michael J. McQuade, COL, DC
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Mar 88 Review Results Continue

Study Objective: To evaluate two combinations of instrumenting proximal root surfaces for efficiency in plaque and calculus removal and attempt to correlate problems with removal of plaque and calculus with access. Also to examine a representative sample of the instrumented surfaces under SEM for desirable and undesirable characteristics of instrumented root surfaces.

Technical Approach: Clean contralateral pairs of teeth in vivo. Extract and analyse root surface with stereomicroscope, photos and computer with digitizing tablet (to calculate areas).

Number of subjects enrolled to date: 18
Number of subjects enrolled during reporting period: 0

Progress: A new method of subgingival calculus removal using an experimental diamond coated tip has been compared to a conventional method with favorable results. The experimental method of calculus removal is just as effective and no more time consuming. It leaves a desirable smooth flowing featured root surface, the experimental method has good tactile feedback, and it eliminates the need for the frequent chairside sharpening of instruments. As a first generation prototype, there is still much room for improvement. More effective ultrasonic instruments can be expected by redesigning the ultrasonic device to optimize cleaning efficiency and developing a variety of special purpose cleaning tips.

Detail Summary Sheet

Date: 2 Jun 88 Prot No.: 87-32		Status: Completed
Title: Evaluation of the Apical Seal Produced by Injected Thermoplasticized Gutta-Percha Using a Gutta-Percha Master Cone.		
Start Date: Mar 87		Est Comp Date:
Principal Investigator(s) Arvid K. Olson, LTC, DC		Facility: Tingay Dental Clinic, DDEAMC
Dept/Svc: Dental Activity		Associate Investigators: R. Norman Weller, COL, DC
Key Words:		Gary R. Hartwell, COL, DC
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: Study is designed to qualitatively and quantitatively evaluate the obturation and apical seal obtained using a master gutta-percha cone and back-filling the canal with injected thermoplasticized gutta-percha. The study will be conducted in vitro using the roots of human teeth which were previously extracted due to caries of other clinical conditions which rendered them non-restorable.

Technical Approach: An evaulation of the apical seal obtained by the combined technique, using a master gutta-percha cone and secondarily filling the canal with injected thermoplasticized gutta-percha, will allow the practitioner to decide whether this technique will adequately seal the root canal system from the attachment apparatus.

Progress: Root canals with large apical foramen were obturated with either high or low temperature injected thermoplasticized gutta-percha after placement of a master gutta-percha cone and sealer. The apical seal produced by these techniques was compared with laterally condensed gutta-percha and with each other in 90 extracted human teeth by ink penetration. Statistical analysis of the results indicated that the high temperature thermoplasticized technique (Obtura) provided an apical seal comparable to that of lateral condensation. The low temperature thermoplasticized technique (Ultrafil) resulted in an apical seal significantly better than the other two techniques.

Detail Summary Sheet

Date: 3 Oct 88 Prot No.: 87-33		Status: Completed
Title: Stereomicroscopic Evaluation of Canal Shape Following Hand, Sonic, and Ultrasonic Instrumentation.		
Start Date: Mar 87		Est Comp Date:
Principal Investigator(s) Robert J. Loushine, MAJ, DC		Facility: Tingay Dental Clinic, DDEAMC
Dept/Svc: Dental Activity		Associate Investigators: R. Norman Weller, COL, DC Gary R. Hartwell, COL, DC
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To evaluate the shape and surface quality of the canal walls following preparation by sonic, ultrasonic, and hand instrumentation.

Technical Approach: This study evaluated the root canal shape after using sonic, ultrasonic, and hand instrumentation on the mesial canals of extracted human mandibular first and second molars. One hundred and five mesial roots were randomly divided into six experimental groups and one control group of 15 roots each. The following instrumentation techniques were evaluated in the experimental groups: hand instrumentation with K-Flex files, sonic instrumentation with the Endostar 5, sonic instrumentation with the Cavi-Endo unit. Each technique was compared with each other. The mesial roots were instrumented alternating the techniques between the buccal and lingual canals in each group so that a direct comparison could be made. All canals were instrumented to a size corresponding to a #30 K-type file 1 mm from the anatomic apex. The roots were then sectioned perpendicular to the long axis so the apical and middle thirds could be evaluated with the stereomicroscope for canal shape. The control group was sectioned and examined without instrumentation.

Progress: Using the signed rank test, there was a significantly more regular shape obtained at both levels with hand instrumentation than that obtained with either sonic or ultrasonic techniques. The comparisons between the sonic and ultrasonic techniques showed significantly better shapes were obtained with the Sonic Air MM 3000 instrument.

Detail Summary Sheet

Date: 2 Jun 88 Prot No.: 87-46		Status: Completed
Title: Presence of Pneumocystis carinii Organisms in the Oral Cavity and Correlation with the Walter Reed Staging Classification of HIV Positive Patients		
Start Date: Jul 87		Est Comp Date: Mar 88
Principal Investigator(s) James N. Hamilton, MAJ, DC		Facility: Eisenhower Army Medical Center
Dept/Svc: Dental Activity, Clinical Investigation		Associate Investigators: Stevan H. Thompson, CPT, DC Michael J. McQuade, COL, DC Michael J. Scheidt, COL, DC Kent M. Plowman, LTC, MC
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To determine the presence of Pneumocystis carinii in the oral cavity and correlate the findings with the severity of periodontal disease and the incidence of Pneumocystis carinni pneumonia in HIV positive patients. The hypothesis is that the oral cavity is a reservoir for the Pneumocystis carinii organism in HIV positive patients and may predispose these immunocompromised patients to Pneumocystis carinii pneumonia.

Technical Approach: Cytology smears from the oral cavity will be examined for the presence of Pneumocystis carinii. The smears will be taken from the tongue, buccal mucosa, pharynx, and dental plaque from HIV positive patients and HIV negative patients. The findings will be correlated to different stages of dental health including healthy gingiva, gingivitis, and periodontal disease.

Number of subjects enrolled to date: 74
Number of subjects enrolled during reporting period: 68

Progress: HIV patients were examined intraorally for clinical findings, and an exfoliative smear technique was performed on four different sites in the mouth. Under light microscopy these smears were examined for the presence of Pneumocystis carinii and for the presence of colonization by Candida sp. This study shows that positive candidal findings and positive clinical findings are both significantly related to a depressed T-cell count. These same findings do not correlate strongly to the Walter Reed Staging Classification System. The oral cavity was not found to be a reservoir for the deadly pathogen of ma. y AIDS patients, Pneumocystis carinii, as this organism was not found in any exfoliative smears.

Detail Summary Sheet

Date: 30 Sep 88 Prot No.: 88-10		Status: Ongoing
Title: Ultrastructural Study of Cultured Human Gingival Fibroblasts Exposed to Ethylene Oxide Sterilized Allogenic Freeze-Dried Bone		
Start Date:		Est Comp Date:
Principal Investigator(s) V. Lawrence Kudryk, MAJ, DC		Facility: Eisenhower Army Medical Center
Dept/Svc: Dental Activity, Clinical Investigation		Associate Investigators: Michael J. McQuade, COL, DC Michael Schiedt, COL, DC Donald E. Sutherland, MAJ, MS
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To determine if residues of ethylene oxide in sterilized freeze-dried allogenic bone are cytotoxic to human gingival fibroblasts.

Technical Approach: Fibroblasts will be evaluated for structural changes using the light microscope and the SEM. Positive controls which have known concentrations of EO will be prepared by exposing Virginia Tissue Bank bone to ethylene oxide. This bone will then be allowed to aerate for various periods of time, allowing time-dependent concentrations of EO, EC and EG to be measured by gas chromatography. The positive controls will be used to determine the relationship between the residue levels of EO, EC, and EG and cellular degeneration. The percentage of cells affected by a given concentration of residual EO (determined by counting the number of cells in a given field which have undergone structural change) will also be used to quantify the effects of the gas. These results will be compared to the effects of the test material on human gingival fibroblast culture.

Progress: To date the research project is progressing on schedule without significant problems or adverse reactions.

Detail Summary Sheet

Date: 30 Sep 88 Prot No.: 88-11		Status: Ongoing
Title: Evaluation of Osseointegration of Titanium Dental Implants in Micro Swine		
Start Date:		Est Comp Date:
Principal Investigator(s) Timothy M. Hale, MAJ, DC		Facility: Eisenhower Army Medical Center
Dept/Svc: Dental Activity, Clinical Investigation		Associate Investigators: Michael J. McQuade, COL, DC Scott L. Strong, LTC, DC
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Sep 88 Review Results Continue

Study Objective: To establish the use of micro swine as a research model for oral endosseous implants. To evaluate the bone-implant interface using Braenmark's titanium implant design in these swine.

Technical Approach: After an initial period of environmental adjustment of the animals, the jaws and teeth will be radiographed and impressed. The mandibular molars and bicuspids will be extracted bilaterally under general anesthesia and allowed to heal for three months. Another surgical procedure will implant Branemark titanium implant fixtures into the edentulous areas. Three fixtures will be placed on one side of the jaw and three on the contralateral side for a total of six fixtures per animal. At three months post extraction the first pig will have all six fixtures placed and the second pig will have three fixtures placed in one half of the jaw. The first pig will be radiographically monitored at monthly intervals throughout the experimental period. At four months post extraction the second pig will have the remaining three fixtures placed. The third pig will have fixture placed 5 months post extraction one one side and 6 months post extraction on the contralateral side. The second and third pigs will be sacrificed 30 days later to yield three specimens each. The implants will be removed en block and histologically prepared for light, scanning electron, and transmission electron microscopy. The contact length fraction, the amount of bone in direct contact with the implant, will be histometrically analyzed for each time interval.

Progress: To date the project is progressing on schedule without significant problems or adverse reactions.

Detail Summary Sheet

Date: 30 Sep 88 Prot No.: 88-12		Status: Ongoing
Title: Experimental Periodontitis in the Micro Swine		
Start Date:		Est Comp Date:
Principal Investigator(s) Bruce A. Boretsky, MAJ, DC		Facility: Eisenhower Army Medical Center
Dept/Svc: Dental Activity, Clinical Investigation		Associate Investigators: Michael J. Scheidt, COL, DC Scott L. Strong, LTC, DC David Turgeon, CPT, MS
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Sep 88 Review Results Continue

Study Objective: To determine whether ligature induced marginal gingivitis in the micro swine will progress to periodontitis if allowed to persist for nine months and to evaluate the changes in the oral flora associated with progression of the disease.

Technical Approach: The micro swine will be stabilized and maintained on a normal laboratory diet. Their periodontal condition will be evaluated and supra-gingival hygiene will be performed under sedation. At day zero the baseline values for gingival index, plaque index, attachment levels, and radiographs will be obtained under general anesthesia., Also at day 0, 2 second molar teeth will be extracted in block section from animal 1 for histologic preparation. Plaque samples will be collected for analysis by phase contrast microscopy and gram stain. Periodontal inflammation will be induced using 3-0 braided silk ligatures placed circumferentially at the gingival margin A contralateral opposing arch design will be employed.

Progress: To date the project is progressing on schedule without significant problems or adverse reactions.

Detail Summary Sheet

Date: 30 Sep 88 Prot No.: 88-13		Status: Ongoing
Title: T4:T8 Lymphocyte Ratios in the Gingiva of AIDS Patients and Uninfected Patient Controls		
Start Date:		Est Comp Date:
Principal Investigator(s) Kenneth E. Steidley, MAJ, DC		Facility: Eisenhower Army Medical Center
Dept/Svc: Dental Activity/Oral Surgery Clinic		Associate Investigators: Stevan H. Thompson, MAJ, DC Michael J. McQuade, COL, DC Scott L. Strong, LTC, DC
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: Compare T4:T8 ratios of the serum of HIV patients to their gingival tissue. Compare T4:T8 ratios of the serum of healthy patients to their gingival tissue. Compare the T4:T8 values of HIV patients to the values of healthy patients.

Technical Approach: When scaling and root planing are performed, a small amount of diseased gingival tissue is normal removed adjacent to the tooth. This diseased tissue will be collected in screens placed in the suction line and will constitute our HIV specimens. Healthy patients that are treatment planned for periodontal surgery will have lab tests for HIV antibodies and T4, T8 peripheral blood lymphocytes done one week prior to surgery. Most periodontal surgical procedures are designed to remove a certain amount of gingival tissue. This tissue will constitute the healthy specimens.

Number of subjects enrolled to date: 8
Number of subjects enrolled for reporting period: 8

Progress: To date the project is progressing on schedule without significant problems or adverse reactions.

Detail Summary Sheet

Date: 30 Sep 88 Prot No.: 88-14		Status: Ongoing
Title: In vivo Study of the Production and Longevity of Dentinal Tubule Occlusion Following Scaling and Root Planing and Application of Oxalate Salts		
Start Date:		Est Comp Date:
Principal Investigator(s) David G. Kerns, MAJ, DC		Facility: Tingay Dental Clinic Eisenhower Army Medical Center
Dept/Svc: Dental Activity, Clinical Investigation		Associate Investigators: Michael J. Scheidt, COL, DC Scott L. Strong, LTC, DC David H. Pashley, DMD, Dental School, MCG
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To study the ability of scaling and root planing alone or scaling and root planing plus the application of potassium oxalate to occlude dentinal tubules, and to determine the persistence of this occlusion in the oral environment over a one month time period.

Technical Approach: Patients with single-rooted teeth slated for extraction prior to the fabrication of a dental prosthesis will participate in this study. Following extraction, one tooth from each patient will be root-planed, sectioned, and incorporated into that patient's denture. Six dentin pieces will be incorporated into the flange of the patient's new denture. The patient will wear the denture and subject it to normal functional use. The remaining dentin pieces will be examined under the SEM to determine for each respective sample the proportion of the surface covered by oxalate occluded tubules, open tubules, or a smear layer. These samples will serve as controls since they will not be exposed to the oral environment.

Progress: To date the project is progressing on schedule without significant problems or adverse reactions.

Detail Summary Sheet

Date: 3 Oct 88 Prot No.: 88-21		Status: Ongoing
Title: An Evaluation of the Apical Seal Produced by Lateral and Lateral Warm Condensation Techniques		
Start Date: Jul 88		Est Comp Date: Dec 88
Principal Investigator(s) Craig T. Luccy, MAJ, DC		Facility: Eisenhower Army Medical Center
Dept/Svc: Dental/Endodontics		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To evaluate the obturation and apical seal obtained using two new electrically heated spreaders.

Technical Approach: Study is designed to qualitatively and quantitatively evaluate the obturation and apical seal obtained using two new electrically heated spreaders. The study will be conducted in vitro using the roots of human teeth which were previously extracted due to caries or other clinical conditions which rendered them nonrestorable.

Progress: All 64 teeth have been collected, root canals instrumented and obturated with gutta-percha, and placed in dye solution to permit any apical leakage. The next step about to be undertaken is the clearing process on these three experimental groups on positive and negative controls which will decalcify the inorganic matrix and allow measurement of the amount of apical leakage.

Detail Summary Sheet

Date: 3 Oct 88 Prot No.: 88-22		Status: Ongoing
Title: The Location of the Mental Foramen: A Comparison of Periapical and Panoramic Radiographs		
Start Date: Apr 88		Est Comp Date: Apr 89
Principal Investigator(s) John L. Phillips, MAJ, DC		Facility: Eisenhower Army Medical Center
Dept/Svc: Dental/Endocontics		Associate Investigators: R. Norman Weller, COL, DC James C. Kulild, LTC
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To compare the visualization and position of the mental foramen between intraoral periapical radiographs and panoramic radiographs.

Technical Approach: The position of the mental foramen was determined on 70 dry mandibles both radiographically (panoramic and periapical views) and clinically, utilizing direct clinical measurements and photographs. Correlation between clinical and radiographic position will be established.

Progress: Collection of data is nearly complete.

Detail Summary Sheet

Date: 3 Oct 88 Prot No.: 88-23		Status: Ongoing
Title: A Standardized Technique for Linear Dye Leakage Studies: Immediate Versus Delayed Immersion Times		
Start Date: Apr 88		Est Comp Date: Apr 89
Principal Investigator(s) Bryan K. Pollard, MAJ, DC		Facility: Tingay Dental Clinic Eisenhower Army Medical Center
Dept/Svc: Dental/Endodontics		Associate Investigators: R. Norman Weller, COL, DC James C. Kulild, LTC, DC
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To evaluate dye leakage into obturated root canals.

Technical Approach: Three groups of 20 roots each are to be obturated in a normal fashion with gutta percha and root canal sealer. The groups are to be immersed in India ink at 0, 1, and 7 days. After the teeth are rendered transparent, a stereomicroscope will be used to measure dye leakage into the obturated roots. A statistical study will be performed to see if there is a significant difference between groups.

Progress: All groups have been obturated. The last group is being rendered transparent. Data collection will begin soon.

Detail Summary Sheet

Date: 17 Oct 88 Prot No.: 87-27 Status: Completed
Title: Lower Extremity Stress Fractures: A Demographic Review of Fort Gordon Military Morbidity and an Analysis of the Role of Crutches.

Start Date: Mar 87	Est Comp Date:
Principal Investigator(s) Mark D. Robinson, MD, CPT, MC	Facility: Eisenhower Army Medical Center
Dept/Svc: Family Practice	Associate Investigators: Claude E. Lett III, CW3, PA
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To analyze all patients with potential lower extremity stress fractures presenting for care at TMC #1, and determine if healing time, and consequently, the time to return to full duty can be shortened by the use of crutches.

Technical Approach: Analysis will be directed toward identifying the historical and demographic features of: age, sex, anatomical location of fracture, prior athletic training, medication use, whether injury occurred in basic training or on Ft Gordon, and whether medical profiles are violated. Patients will be randomly assigned to treatment either with or without crutches on the initial visit.

Number of subjects enrolled to date: 117
Number of subjects enrolled for reporting period: 17

Progress: A total of 117 patients were evaluated during routine military sick call. Of these, 74 patients were referred for diphosphonate bone scanning with 57 scans (77%) positive for stress fracture. Potential femoral neck stress fractures were excluded. The distribution of the stress fracture by anatomical site revealed 51.0% tibial, 12.8% tibio-talar, 12.8% femur, 9.0% metatarsal, 6.0% tarsal, 5.3% patellar, 2.3% patellar, 2.3% pelvic and 0.8% fibular. Patients with prior high school varsity athletic participation had a lower average number of bones with stress changes that those without: 1.72 vs 2.80 ($p<.005$).

Twenty-five patients (44%) returned to full duty in less than ten weeks: 20 (35%) required more than ten weeks to heal and 12 (21%) were lost to follow-up. In the group healing within ten weeks, those randomly assigned to crutches had a reduced healing time by an average of 11 days ($p<0.07$).

Detail Summary Sheet

Date: 1 Oct 88 Prot No.: 87-53		Status: Completed
Title: Infant Exposure to Tobacco Smoke Pollution: A Trial of Educational Intervention		
Start Date: Oct 87		Est Comp Date: Sep 88
Principal Investigator(s) Wiley A. Smith, MD, MAJ, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Family Practice		Associate Investigators: Ronald J. Edwards, MD, LTC, MC
Key Words: Tobacco smoke pollution, High performance liquid chromatography Passive smoking, Cotinine, Patient Education		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: 1) What is the correlation between an infant's urinary cotinine and the reported smoking habit of the parents? 2) Do mothers who decrease or stop smoking during pregnancy resume smoking afterwards? 3) Are infants who are breast fed by smoking mothers exposed to more nicotine than those who are not? 4) Are parents knowledgable of the adverse effects of tobacco smoke on their infants? 5) Can an educational intervention reduce infant exposure to tobacco smoke? 6) Can an educational intervention increase parental knowledge of adverse effects?

Technical Approach: Information from the parents will be gathered, to include the parent's personal smoking habits, smoking during pregnancy, breastfeeding, and awareness of potential health consequences. This data will be correlated with an objective measurement of tobacco smoke exposure, the urinary cotinine to creatinine ratio. Infants and their families will be randomly assigned to either an intervention or control group.

Number enrolled to date: 40
Number of subjects during reporting period: 40

Progress: Of 40 infants from both groups, 25 (63%) had detectable levels of cotinine on the initial urine sample. The urinary cotinine to creatinine ration ranged from 0 to 1047 ng/mg, with a mean of 128. The ratio correlated to the mother's smoking habit (Pearson's $r = 0.37$, $p < 0.02$), but not with the father's habit ($r = .05$). Most mothers who were current smokers had also smoked during pregnancy. After delivery, 67% of smoking mothers increased their habit, 20% retained the same habit, and 13% decreased their habit in comparison to smoking while pregnant.

Our educational efforts were successful in increasing parental knowledge of tobacco smoke's deleterious effects on young infants, but not in influencing exposure levels as we measured them. As shown in many other studies, nicotine addiction is difficult to eradicate solely by education.

The urinary cotinine to creatinine ration was a useful measure of children's exposure to tobacco smoke. Since the ratio correlated best with the mother's

87-53 Continued

smoking habit, future educational efforts should be concentrated on the mother. Most smoking mothers reduce or quit during pregnancy, only to resume their habit post-partum. Encouragement for women not to smoke should be a standard for immediate post-partum education.

Smith WA: Effects of parental education on passive smoking exposure of infants. Presented at Conf Patient Education Primary Care Setting, Kansas City, MO, 15-17 Sep 1988, and submitted to Family Medicine.

Detail Summary Sheet

Date: 25 Sep 88	Prot No.: 88-7	Status: Ongoing

Title: Relationship of Maternal Body Fat Composition to Pregnancy Outcome.

Start Date:		Est Comp Date:
Principal Investigator(s) Ronald J. Edwards, MD, LTC, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Family Practice		Associate Investigators: Wiley Smith, MD, MAJ, MC
Key Words		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: This study will describe the relationship of maternal prenatal nutritional status as reflected by maternal body fat composition, to specific outcome variables (maternal hypertension, maternal height and weight, increased bleeding during labor and delivery, preeclampsia, excess pregnancy weight gain, prolonged labor, birth weight, fasting blood sugar at onset of pregnancy, O'Sullivan value at 28 weeks and maternal blood pressure). Prenatal weight gain has long been a parameter followed during adequate monitoring of pregnancy, but many variables join to determine overall weight gain (ie, fetal size, volume of amniotic fluid, maternal fluid retention). Change in body fat composition during the course of pregnancy has not been well described in the literature; this definition is anticipated to add to the true descriptive picture of adipose tissue content of the pregnant woman.

Technical Approach:

1. Summary of experimental design: Body fat content is an important indicator of nutritional status in health and disease. The most reliable measurement of body fat is the underwater weighing technique because it generally eliminates most of the measurement errors and is felt to come closest to telling the truth about the true percentage of the body composition made up by fat tissue. However, it is cumbersome, generally unavailable, and for some studies and subjects, impractical or impossible. Other methods of body fat measurement (BFM) that have been investigated include anthropometry, isotope dilution, ultrasound, computed tomography, magnetic resonance imaging, and neutron activation. Each of these methods has interesting possibilities or advantages but most are limited by the cost or availability of the equipment or by the invasive nature of the testing procedure leaving anthropometry and electrical impedence as the available, affordable and usable (ie, no invasive threat to the mother or fetus) modes in the current study. (Bray, Contemporary Nutrition.)

All patients enrolled for obstetrical care at the Family Practice Clinic at DDEAMC who are willing to participate in the study are included as subjects, until 50 subjects are identified. These subjects have both skin caliper and electroplythesmography (EPG) measurements made at the time of their first evaluation. At each month thereafter during their pregnancy, their body content is to be analyzed by the EPG method. At the postpartum visit at 6 weeks and 6 months, both skin caliper and EPG measurements will again be made.

88-7 Continued

Additional data to be gathered on each subject includes height, weight, birth weight of the baby, single or multiple birth, O'Sullivan scores (at the standard 16 and 36 week milestones), initial fasting blood sugar, blood pressure at each body fat measurement interval, presence of abnormal bleeding during labor, length of labor stages (1,2,3,4), the presence of preeclampsia/eclampsia, and the method of feeding of the newborn. All of these variables are already being measured by the standard obstetrical care protocol and so involve no additional testing of the subject.

Longitudinal progress of body fat is calculated through the course of the pregnancies, using multiple analysis of variance techniques to consider the variables named above. Adjustments will be made for age, parity, and prepregnancy body fat content. A separate analysis will be made of the rate and extent of return to prepregnancy body fats.

1. Manpower: The only manpower employed (available) has been the investigator and the RN. Some administrative assistance has also been available and the ordinary nursing care used to gather routine obstetrical data has been in place.

3. Funding: Only office supplies and data gathering time and minimal computer time have been expended.

Number of subjects enrolled to date: 43
Number of subjects enrolled for reporting period: 43
A new target of 50 total subjects has been adopted because of the extended time being required to gather subjects and the uniformity of the data so far gathered.

No adverse reactions have been recognized.

Progress: Because of a lack of supportive manpower, data gathering has been slow. The measurements are being done exclusively by the investigator, a benefit to standardization and reduction of measurement error, but a definite barrier to speedy progress. An anticipated finishing date is now projected to be summer 89.

Presentation: University of Texas Annual Family Practice Research Conference, Houston, TX, 4-5 August, 1988.

Detail Summary Sheet

Date: 27 Sep 88	Prot No.: 88-8	Status: Ongoing
Title: Effect of Patient Education of Cholesterol Level		

Start Date: Apr 88		Est Comp Date: Apr 89
Principal Investigator(s) Bruce A. Leibert, M.D., CPT, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Family Practice		Associate Investigators: Louis J. Irwin, M.D., CPT, MC Steven G. Lang, M.D., MAJ, MC Rhonda L. Podojil, R.D., 2LT, SP
Key Words: Cholesterol education		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To determine whether an intensive program of patient education and dietary counseling is more effective in lowering total serum cholesterol in adults than education with written material only.

Technical Approach: The Student's t-test for unpaired data is being used to analyze our data.

Number of subjects enrolled to date: 60
Number of subjects enrolled during reporting period: 60

Progress: The 27 patients who have completed the first three months of our study period have shown these results: mean change in total cholesterol was 15 for the study group and .3 for the control group ($p < 0.1$). The mean change in LDL-cholesterol was 12 for the study group and 3 for the control group ($p < .2$).

As more results come in, I believe we will see the p value reach statistical significance. Also, we plan to continue every three month lipid profiles on the patients in order to assess long-term adherence to dietary modification. The followup will last 12 months total.

This project has been presented twice:

a. Leibert BA: Cholesterol level and patient education. USAFP Mtg, Salt Lake City, UT, 29 Mar 1988.

b. Leibert BA: Cholesterol education in small group stations. STFM Patient Ed Mtg, Kansas City, MO, 16 Sep 1988.

Detail Summary Sheet

Date: 3 Oct 88 Prot No.: 78-38		Status: Ongoing
Title: Efficacy of Immunotherapy for Systemic Allergic Reaction to Imported Fire Ant Stings. Human Immunologic Reactivity to Fire Ant Antigens. BB IND 1452, Part II, III		
Start Date: Feb 85		Est Comp Date:
Principal Investigator(s) Antonio L. Bunker-Soler, LTC, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Medicine/Immunology		Associate Investigators: Robert B. Rhoades, MD, Medical College of Georgia
Key Words:		Chester T. Stafford, MD, Medical College of Georgia
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Mar 88 Review Results Continue

Study Objectives: a. To ascertain the relative efficacy of immunotherapy with whole body extracts and venom compared to placebo in the treatment of systemic hypersensitivity to stings of the imported fire ant.

b. To ascertain the natural history of imported fire ant hypersensitivity and to identify possible subgroups who may undergo spontaneous desensitization and not require immunotherapy.

Technical Approach: Experimental design: Patients found to be allergic to fire ants by history and laboratory parameters will be placed on placebo, whole body extract or venom. After approximately eight weeks, patients will be hospitalized for repeat laboratory parameters and challenge to fire ant bite. Depending on outcome, adjustment of treatment will be done accordingly.

Number of subjects enrolled to date: 7
Number of subjects enrolled for reporting period: 0

Progress: Study on hold due to PCS of Dr. Bunker-Soler and awaiting new investigator.

Detail Summary Sheet

Date: 4 Oct 88	Prot No.: 83-22	Status: Ongoing
Title: Use of Isotretinoin in Prevention of Basal Cell Carcinoma		

Start Date: Feb 85		Est Comp Date:
Principal Investigator(s) Marshall A. Guill, MD, COL, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Medicine/Dermatology		Associate Investigators: John R. Cook, MD, COL, MC
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Mar 88 Review Results Continue

Study Objective: To evaluate the effectiveness of low dosage levels of Isotretinoin in reducing the incidence of basal cell carcinomas in a high risk population. To examine possible side effects associated with long term administration of low doses of Isotretinoin.

Technical Approach: Patients with two or more basal cell carcinomas (BCC) in the past five years are eligible for inclusion in the study. They must be between the ages of 40 and 75 and incapable of bearing children. After a thorough physical examination, including basic laboratory data, participants are randomized to either the treatment group of the placebo group. The medication is provided by the National Cancer Institute and is double-blinded. Participants take medication for 36 months, continuing to be followed for the following 24 months for a total of 60 months in the study.

Funding: A total of $39,500 was provided this fiscal year by NCI. This included an increase of $6,100 to cover escalating costs of the study coordinator's salary and retirement benefits.

Number of subjects enrolled to date: 132
Number of subjects enrolled for reporting period: 1

Progress: Our initially randomized patients began completing the medication phase of the study and we have completed 50 of the 36-month physicals. There have been no new signs of DISH or any new lab abnormalities. There has been concern by a few patients that they may begin to get more BCC's now that they are off medication and are reluctant to stop! They also anxiously await the unblinding in June 1990. We have accepted in transfer one patient from Portsmouth Naval Hospital who is off medication. one patient has gone off medication and was lost to followup after he had open heart surgery, two strokes, and then moved from the area. Another patient who had completed the medication phase was lost to followup after she moved from the area. We currently follow 121 patients on or off medication.

83-22 Continued

During the past year, we have continued to experience some problems with the air conditioning and heating, but the building has been rewired for a safer environment. We have received a copy machine, laser printer and a computer which were purchased with NCI funds.

We continue to follow randomized patients at Hunter Army Air Field every six months in Savannah, Georgia.

The ancillary support from Laboratory, X-ray and Pathology departments at DDEAMC, Ft MacPherson, Hunter Army Air Field and Ft Stewart continues to be excellent.

Additional funds from NIH were required this fiscal year to cover salary increases for the study coordinator. The study has received approval for a three year extension through September 1991 with a total budget of $176,397. The budget for FY 1989 is $58,326.

COL Aton has retired; the principal investigator, COL Marshall A. Guill, MC and COL John R. Cook, MC remain as clinic staff. Civilian Personnel Office is currently working on getting an extension on the study coordinator's term job status.

The compliance continues to remain outstanding. One problem patient has improved his compliance greatly with monthly phone calls and pill counts.

Our patients have experienced very few adverse reactions. No one's medication has been permanently discontinued in the past year. One patient died from stomach cancer. Two patients were temporarily off medication while awaiting extensive neurological and gastrointestinal workups. Another patient complained of dry eyes and chose to go on dose modification, dechallenge and rechallenge to see if it helped his eyes. He had this problem intermittently and wanted to make sure it wasn't related to the study medicine. Two more patients have been placed on dose modification to one pill - one for dry lips and one for elevated SGOT. In summary, of the present 121 patients being followed: 51 are off medication because they have completed the medication phase; 4 are on dose modification to one pill for possible cutaneous side effects; 5 are on dose modification to one pill for possible non-cutaneous side effects; and 4 are off medication for possible non-cutaneous side effects.

Detail Summary Sheet

Date: 28 Oct 88 Prot No.: 87-1		Status: Ongoing
Title: Causes of Transient Myocardial Ischemia in Asymptomatic and Symptomatic Patients with Coronary Artery Disease.		
Start Date:		Est Comp Date:
Principal Investigator(s) George S. Rebecca, MD, LTC, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Medicine/Cardiology		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Mar 88 Review Results Continue

Study Objective: To assess the sensitivity of different segments of epicardial coronary arteries in patients using quantitative coronary arteriography and to measure by computer the responses of epicardial coronary arteries.

Technical Approach: Up to now non-specific provocations and severe technical deficiencies have limited the resolutions of pathophysiological events and hindered attempts to find specific causes of ischemia. The proposed aims to answer: 1) The relative importance of physical activity; mental arousal and truly spontaneous events in the genesis of ischemia in normally active patients out of hospital. For this purpose clinical characterization, diaries and frequency modulated Holter monitoring of the electrocardiogram will be performed in well characterized patients; 2) The second aim is to use quantitative angiography, myocardial oxygen demand and incidence of ischemia to study patients at cardiac catheterization in order to examine the initial causes of sequence of events triggering ischemia during maneuvers that are related to events outside the hospital.

Number of subjects enrolled to date: 60
Number of subjects enrolled for reporting period: 60

Progress: We have enrolled 50 patients in the Holter part of the study which was the basis for an abstract at the Army ACP Meeting. There have been 10 patients enrolled in the Cath Lab part of the study.

Detail Summary Sheet

Date: 22 Mar 88 Prot No.: 87-2		Status: Terminated
Title: Comparison of Intravenous Abbokinase and Streptokinase in the Treatment of Acute Myocardial Infarction.		
Start Date:		Est Comp Date:
Principal Investigator(s) George S. Rebecca, MD, LTC, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Medicine/Cardiology		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Mar 88 Review Results Terminate

Study Objective:

Technical Approach:

Progress: Unable to implement due to inability to obtain Jackson Foundation agreement for funding, company dropped DDEAMC from study.

Detail Summary Sheet

Date: 28 Oct 88 Prot No.: 87-3		Status: Ongoing
Title: Evaluation of Dynamic Rate Response Pacing, Incidence of Myocardial Ischemia and Reaction of Epicardial Coronary Arteries.		
Start Date:		Est Comp Date:
Principal Investigator(s) George S. Rebecca, MD, LTC, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Medicine/Cardiology		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Mar 88 Review Results Continue

Study Objective: To evaluate the effect of dynamic rate responsive pacing in patients with proven coronary artery disease; to determine the effect on silent myocardial ischemia vs control/traditional modes of pacing and to evaluate the epicardial coronary reactivity with regards to changes in cross-sectional area and proximal coronary blood flow with increased pacing rate at cardiac catheterization.

Technical Approach: The study will be performed using quantative angiography and ST Segment FM Holter Monitoring. We will study patients for the angiography part of the protocol; some with abnormal coronary artery disease and some normals. We will also study a group with coronary disease off medication; a group with rate responsive pacemakers; a group with a traditional pacemaker; and a group with no pacemaker therapy. The age range will be 35 to 75 years of age with chronic stable angina.

Number of subjects enrolled to date: 0

Progress: This study is still on hold waiting for the QCA equipment to be functional. We have enrolled no patients.

Detail Summary Sheet

Date: 28 Oct 87 Prot No.: 87-7		Status: Terminated
Title: The Detection of Epithelial Dysplasia by Light and Scanning Electron Microscopy in Patients with Barrett's Esophagus		
Start Date: Dec 86		Est Comp Date: Dec 88
Principal Investigator(s) Howard M. Rosen, MD, COL, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Medicine/Gastroenterology Service		Associate Investigators: William T. Brand, Jr., MD, MAJ, MC
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: 1) To utilize light microscopy and scanning electron microscopy to confirm the presence of metaplasia, and 2) to identify a subgroup of patients with Barrett's esophagus with severe dysplasia and correlate the light microscopic findings for metaplasia and dysplasia with the scanning electron microscopic features.

Technical Approach:

Number of subjects enrolled to date: 2

Progress: Unable to find the necessary subjects. Terminate at investigator's request.

Detail Summary Sheet

Date: 3 Oct 88	Prot No.: 87-49	Status: Completed
Title: A Survey of the Sexual Practices of HIV Antibody Seropositive Patients		
Start Date: Oct 87		Est Comp Date: Jul 88
Principal Investigator(s) Roberto N. Nang, MD, CPT, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Medicine		Associate Investigators: David R. Haburchak, MD, COL, MC
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To determine among a group of patients that are HIV antibody serpositive: 1) how prevalent are the patients' sexual orientation to homosexuality vs bisexuality vs homosexuality based on Kinsey's graded scale of sexual orientation; 2) how many different partners and how many different sexual encounters they may have had within a given time period; 3) how common a variable is: a) anal (receptive vs insertive) intercourse, and b) oral (passive vs active participation among these patients; 4) how common a variable among these patients is involvement with a prostitute; 5) after these patients were informed of their HIV serpositivity and after being informed of its consequences, what, if any, changes have been made in their sexual practices.

Technical Approach: The responses of the subjects who take the HIV medical survey will be summarized and compared using both descriptive and inferential statistical analyses. Associations between various groups will be examined (t-test for one-way analysis of variance, Chi-square, Pearson r correlation coefficients, and nonparametric Spearman rank order correlation).

Number of subjects enrolled to date: 90
Number of subjects enrolled for the reporting period: 90

Progress: This study has been completed with 90 subjects enrolled and survey forms completed. Data analysis has been hampered by the PCS of Dr. Nang to Madigan Army Medical Center for his Preventive Medicine Fellowship. Data analysis will be complete in approximately two months.

Detail Summary Sheet

Date: 1 Jun 88 Prot No.: 87-51		Status: Transfer
Title: The Effectiveness of Metroclopramide to Improve Colonic Visibility in Patients Receiving Night Prior Colonic Lavage: A Double Blind Randomized Study		
Start Date: Oct 87		Est Comp Date: Oct 88
Principal Investigator(s) Peter R. McNally, DO, MAJ, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Medicine/Gastroenterology		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To evaluate if the addition of metroclopramide to the standard overnight colonic lavage solution is effective in improving visibility during colonoscopy - a placebo controlled trial.

Technical Approach: All patients will receive either metroclopramide or placebo. Visibility parameters will be assessed in accordance with an established scheme. Duration of procedure will be recorded for all patients.

Number of subjects enrolled to date: 38
Number of subjects enrolled during reporting period: 38

Progress: This study will be continued at WRAMC (GI SCU) until a total of 100 patients have been accrued. Study monitor at WRAMC will be David Peura, COL, MC, Chief, GI, WRAMC.

Detail Summary Sheet

Date: 26 Sep 88	Prot No.: 88-2	Status: Ongoing

Title: A Prospective Double-Blind Study of Retrovir in Early HIV Infection

Start Date: Nov 87	Est Comp Date: Oct 90
Principal Investigator(s) David R. Haburchak, M.D., COL, MC	Facility: Eisenhower Army Medical Center
Dept/Svc: Medicine/Infectious Disease	Associate Investigators: D. Baxter Craig, M.D., LTC, MC
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To determine what effect the investigational new drug Retrovir (AZT) has on the course of infection with HIV.

Technical Approach: This will be a placebo-controlled, double-blind study to evaluate the effect of 800 mg/day of oral Retrovir on the clinical, immunologic and virologic manifestations of early HIV disease. Patients entering this trial will have signs and symptoms consistent with early stages of the disease and CD4 cell number $\geq$ 200. The safety and tolerance of Retrovir in this population will also be evaluated. Eligible patients will be randomized to receive either Retrovir or placebo capsules for an initial 48 week period. Study medicines will be administered at a dose of 200 mg every 6 hours.

Number of subjects enrolled to date: 5
Number of subjects enrolled during reporting period: 5

Progress: This study has accumulated approximately 200 patients between Fitzsimons and the University of Colorado at Denver, five patients having been contributed from Eisenhower/Ft McPherson for a double-blind study of Retrovir in early HIV infection. All five patients are followed by COL Haburchak on a monthly basis at Ft McPherson, and by Dr. Harrison from Fitzsimons on a monthly basis. There have been no drop outs or untoward effects apparent from medication or placebo. The study is ongoing and patients will continue to be followed until they fall below 200 CD4 cells at which time AZT will be given. Studies anticipate to continue for another two years with no additional input from Eisenhower.

Detail Summary Sheet

Date: 28 Sep 88 Prot No.: 88-3		Status: Ongoing
Title: Retreatment of Idiopathic Membranous Glomerulopathy Using Steroids and Chlorambucil After Initial Unresponsiveness to Alternate-Day Steroids		
Start Date: Nov 87		Est Comp Date: Sep 89
Principal Investigator(s) David P. Tietjen, M.D., MAJ, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Medicine/Nephrology		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To assess the merits of an alternative treatment regimen for idiopathic membranous glomerulopathy in inducing a response after an unsuccessful attempt using an older form of therapy.

Technical Approach: Patients enrolled if they meet entry criteria, no randomization. They receive alternate months of prednisone and chlorambucil for six months.

Number of subjects enrolled to date: 1
Number of subjects enrolled for reporting period: 1

One subject terminated from protocol due to adverse reaction to corticosteroids (reported 12/87).

Progress: One subject has completed therapy (3 months ago) and has had a marked improvement, now has normal albumin, no edema, 24 hour protein excretion of 4.5 g (pretreatment > 10 g).

Will enroll additional patients if any are found.

Preparation of case report is planned and underway.

Detail Summary Sheet

Date: 19 Sep 88 Prot No.: 88-4 Status: Terminated
Title: Comparison of Venous Impedance Plethysmography With Contrast

Start Date:		Est Comp Date:
Principal Investigator(s) David P. Ciceri, M.D., CPT, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Medicine		Associate Investigators: D. Baxter Craig, M.D., LTC, MC
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To establish the sensitivity and specificity of venous impedance plethysmography (IP) in the diagnosis of proximal vein deep venous thrombosis (DVT) as compared to contrast venography.

Technical Approach: Plethysmography was performed in conjunction with venograms in patients with suspected deep venous thrombosis.

Number of subjects enrolled to date: 3
Number of subjects enrolled for reporting period: 3

Progress: The study was terminated due to transfer of the principal investigator.

Detail Summary Sheet

Date: 3 Nov 88 Prot No.: 88-15		Status: Ongoing
Title: Evaluation of Polypharmacy on Internal Medicine Ward		
Start Date: Jan 88		Est Comp Date: Feb 89
Principal Investigator(s) Mark Marino, MD, CPT, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Medicine		Associate Investigators: David R. Haburchak, MD, COL, MC
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To establish frequency distribution and causes of polypharmacy in medical patients on the Eisenhower Army Medical Center wards. To ascertain common drug incompatibilities and potentially risky combinations of medications and to establish educational guidelines for the prevention of polypharmacy.

Technical Approach: Analysis of pharmacy lists of all medicine inpatients from Jan 88 to Sep 88 for those at risk for polypharmacy identifying potential drug-drug interactions and correlating with diagnosis and physician reporting of drug-drug interaction/reaction.

Progress: To date 909 patient days have been analyzed with 386 at risk patient days (i.e., polypharmacy) and 325 potential drug-drug interactions. Approximately 2000 more patient days will need to be analyzed and then approximately 1000 patient days (approximately 150-200 patients) will be cross referenced from inpatient summaries as to diagnoses and in-hospital complications from drug-drug interactions (reactions).

One benefit from the study has been a heightened awareness of drug-drug interaction, and the reporting of a potential low drug-drug interaction which has been accepted for future publication in Drug Intelligence and Clinical Pharmacy.

Detail Summary Sheet

Date: 26 Sep 88 Prot No.: 88-18		Status: Ongoing
Title: A Prospective Evaluation of HIV Patients for Evidence and Treatment of Neurosyphilis		
Start Date: Feb 88		Est Comp Date:
Principal Investigator(s) David R. Haburchak, MD, COL, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Medicine/Infectious Disease		Associate Investigators: Robert E. Morrison, MD D. Baxter Craig, MD, LTC, MC William Clayton, FAMC Danny J. Lancaster, MD
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: Assessment will be made of the prevalence of previous and active syphilis, including neurosyphilis, in patients with HIV at three medical centers. Also assessment will be made of oral therapy of neurosyphilis in HIV patients.

Technical Approach: Patients must be HIV positive by ELISA and Western Blot, adult, over 18 years of age, and seropositive by FTAABS. Patients will be included whether treated or not previously treated for syphilis. Patients will have histories determined for previously sexually transmitted diseases, syphilis and syphilis-like symtomatology and specific therapies previously undertaken for both syphilis and HIV. Where possible records will be obtained from public health authorities to confirm treatments given. Patients will be taken in all stages of HIV infection and stratified by stage.

Number of subjects enrolled to date: 9
Number of subjects enrolled during reporting period: 9

Progress: To date Fitzsimons and University of Tennessee have not contributed patients to this study and they are not likely to do so. We have enrolled nine patients all of whom have completed the initial phase of lumbar puncture and were treated without untoward effect with Amoxicillin. One patient had repeat lumbar puncture performed post therapy with no significant change in his spinal fluid parameters. The remainder of patients have not had repeat or followup punctures.

Detail Summary Sheet

Date: 28 Oct 88 Prot No.: 88-19		Status: Ongoing
Title: Evaluation of Nitroglycerin Therapy in Patients with Asymptomatic Coronary Artery Disease and Silent Ischemia		
Start Date:		Est Comp Date:
Principal Investigator(s) George S. Rebecca, MD, LTC, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Medicine/Cardiology		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To determine the effectiveness of Transderm-Nitro in abolishing "silent" ischemia in subjects with documented but asymptomatic coronary artery disease.

Technical Approach: The frequency and duration of ischemic episodes will be measured by analysis of ST segments recorded during ambulatory ECG monitoring. An ischemic event will be defined as horizontal or downsloping ST segment depression lasting for 60 seconds or longer. The depth of the depression must be 1 or more mm from the baseline established by the TP or PR interval as measured 80 msec from the J point. Monitoring will be performed in the lead demonstrating maximum ST depression during exercise testing.

Number of subjects enrolled during reporting period: 0

Progress: This study is about to start since we will soon be funded by the Jackson Foundation.

Detail Summary Sheet

Date: 28 Oct 88 Prot No.: 88-24		Status: Ongoing
Title: Pathophysiology of Coronary Artery Dilatation		
Start Date:		Est Comp Date:
Principal Investigator(s) George S. Rebecca, MD, LTC, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Medicine/Cardiology		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To attempt to confirm that the normal response to increased coronary blood flow is endothelium-dependent epicardial artery dilation and that in atherosclerosis this important endothelial function is not lost.

Technical Approach: We plan to study adult male and female patients ages 18 to 75 years who present with chest pain, a stable clinical course and suitable coronary anatomy at diagnostic catheterization. Patients with smooth (n=10), irregular (n=10), and stenosed (n=10) left anterior descending or non-dominant circumflex arteries will be studied. Twelve hours prior to catheterization, long acting nitrates, calcium-channel blockers, beta-blockers an dipyridamole will be held. Following diagnostic venous and arterial catheterization, including coronary arteriography, a 5 French pacing wire is placed in the right ventricle and an 8 French Judkins catheter is positioned in the ostium of the left coronary artery. A 2.5 French intracoronary Doppler catheter is positioned in the proximal left anterior descending or non-dominant circumflex artery and an additional 5,000 units of Heparin is given intravenously. Baseline coronary blood flow velocity, hemodynamics and a biplane coronary angiogram will be performed using non-ionic contrast (Omnipaque).

Number of subjects enrolled to date: 4
Number of subjects enrolled for reporting period: 4

Progress: We have enrolled four patients to date, using two for the basis of a recent abstract presented at the Army ACP meeting.

Detail Summary Sheet

Date: 28 Oct 88 Prot No.: 88-25		Status: Ongoing
Title: Endothelial Dysfunction of Coronary Resistance Vessels		
Start Date:		Est Comp Date:
Principal Investigator(s) George S. Rebecca, MD, LTC, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Medicine/Cardiology		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To determine whether endothelial dysfunction in the microvasculature of patients with cardiomyopathies might be a cause of microvascular vasospasm manifested as inadequate vasodilator reserve.

Technical Approach: Patients admitted to the hospital with the diagnosis of hypertrophic cardiomyopathy, dilated cardiomyopathy, left ventricular hypertrophy due to hypertension and patients who may have normal hearts at the time of diagnostic heart catheterization will be asked to participate in the study. Twenty-four hours prior to catheterization, nitrates, calcium-channel blockers, and beta-blockers will be withheld. Following diagnostic venous and arterial catheterization, including coronary arteriography, a 5 French pacing wire will be positioned in the right atrium and an 8 French Judkins catheter will be positioned in the ostium of the left coronary artery. A 2.5 French intracoronary Doppler catheter is positioned in the proximal left anterior descending coronary artery and an extra 5000 units of Heparin will be given intravenously. Baseline coronary blood flow will be measured and a baseline coronary angiogram will be performed using non-ionic contrast (Omnipaque). We will evaluate coronary blood flow changes to intracoronary administration of acetylcholine and adenosine to assess small vessel endothelial function.

Number of subjects enrolled to date: 0
Number of subjects enrolled during reporting period:

Progress: This study is waiting for the QCA equipment to be functional.

Detail Summary Sheet

Date: 21 Sep 88 Prot No.: 88-26		Status: Completed
Title: Evaluation of Possible Subclinical Rhabdomyolysis in Active Duty Soldiers Performing the APFT		
Start Date: Jun 88		Est Comp Date:
Principal Investigator(s) Louis M. Guzzi, MD, CPT, MC David P. Tietjen, MD, MAJ, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Medicine/Nephrology, Clinical Investigation		Associate Investigators: Donald E. Sutherland, MAJ, MS
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To establish a potential early detection system of predicting that an individual is at an increased risk of developing post-exertional rhabdomyolysis or requires more frequent scrutiny post APFT.

Technical Approach: A prospective cohort study of soldiers during Advanced Individual Training (AIT) with each soldier receiving a questionnaire prior to the study. Each soldier had serum and urine sample obtained prior to APFT, and at 6 and 24 hours after the APFT.
Number of subjects enrolled to date: 78
Number of subjects enrolled during reporting period: 78

PARTICIPANTS: Seventy-eight active duty male soldiers currently in AIT between the ages of 18-26 with no pre-existing medical conditions noted. Fifty-six of the soldiers were unconditioned and 22 of the soldiers were conditioned.

MEASUREMENTS AND MAIN RESULTS: The elevation of myoglobin in the urine, creatine kinase, BUN, creatinine with statistical significance in each value at 6 hours and 24 hours was not unexpected. The values did demonstrate a smaller increase in myoglobinuria in those individuals assumed to be preconditioned. No individual demonstrated a significant increase in adenosine deaminase binding protein in either group. A urine Ames Multistix SG dipstick with the Ames Multistix did not reveal any significance of positive results even with the mild elevation in myoglobin.

CONCLUSIONS: While increases in serum levels of BUN, creatinine, CPK and myoglobin can be expected up to 24 hours post physical exertion, the levels to which they rise while being statistically significant are probably not clinically relevant in this patient population. The use of ABP as a marker for renal damage in the population under study was either not sensitive enough, or the individuals were not stressed maximally and urinary ABP levels probably would not suffice as a simple screen for renal tubular damage in these patients. The risk of rhabdomyolysis in those soldiers undergoing routine APFT is probably small.

Guzzi LM, Tietjen, DP, Sutherland DE: Assessing the potential risk of renal dysfunction secondary to subclinical rhabdomyolysis induced by exercise. Submitted to Ann Intern Med.

Detail Summary Sheet

Date: 29 Sep 88 Prot No.: 88-27		Status: Ongoing
Title: Comparison of Cholesterol Lowering Properties of Psyllum Hydrophilic Mucilloid and Cholestyramine		
Start Date: 19 May 88		Est Comp Date: May 89
Principal Investigator(s) Arnold A. Asp, MD, MAJ, MC Mark A. Smith, MD, CPT, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Medicine, Clinical Investigation		Associate Investigators:
Key Words: Cholesterol, Cholestyramine, Psyllum		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To compare the cholesterol lowering efficacy of cholestyramine, PHC and PHC/cholestyramine combination, and to assess degree of compliance, cost effectiveness and adverse effects of each regimen.

Technical Approach:
a. Design - Double blinded controlled prospective study.
b. Manpower - This study will require 2-4 hours per week of one Medical resident (Dr. Smith) and one Staff Endocrinologist (Dr. Asp). Appropriate support by Pharmacy and Pathology has been coordinated through MAJ Almquist and COL Goodhue.
c. Funding: $6500.00

Number of subjects enrolled to date: 3
Number of subjects enrolled during reporting period: 3
Nature of adverse reactions: None.

Progress: After approval of the protocol, difficulties in obtaining the appropriate drug containers was encountered. This program led to curtailment of subject recruitment over the past 30-60 days. Appropriate containers and sufficient amounts of study drugs have been procured and it is anticipated that 3-5 new subjects per week will be enrolled.

Detail Summary Sheet

Date: 28 Sep 88 Prot No.: 88-28		Status: Ongoing
Title: The Relationship Between Total Ultrafiltration Volume During Hemodialysis and Hemoconcentration as Indicated by RBC Measurements and serum Protein Concentration		
Start Date: Apr 88		Est Comp Date: Sep 89
Principal Investigator(s) David P. Tietjen, MD, MAJ, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Medicine/Nephrology		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To study chronic incenter hemodialysis patients with consecutive treatments over a one-month period. Will search for any relationship between hematologic parameters or serum albumin and measures of body weight change.

Technical Approach: Data will be obtained from chronic incenter hemodialysis patients via measurement of blood test results and recording physical parameters which are normally measured during routine hemodialysis.

Number of subjects enrolled to date: 0
Number of subjects enrolled during reporting period: 0

Progress: Project has not been started due to lack of physician manpower.

Detail Summary Sheet

Date: 28 Oct 88 Prot No.: 88-29		Status: Ongoing
Title: Clinical Multicenter Evaluation of Nifedipine GITS in Reducing the Total Ischemic Burden and Suppressing the Circadian Ischemic Surge in Patients with Symptomatic Coronary Artery Disease		
Start Date:		Est Comp Date:
Principal Investigator(s) George S. Rebecca, MD, LTC, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Medicine/Cardiology		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To try to clarify some of the issues regarding mechanisms of action of a new delivery system nifedipine GITS (Gastrointestinal Therapeutic System) compared to other antianginal therapies.

Technical Approach:

Number of subjects enrolled to date: 0
Number of subjects enrolled during reporting period:

Progress: Study has not started. We are waiting for final approval of financial agreement between Pfizer and the Jackson Foundation. All other paperwork has been completed.

Detail Summary Sheet

Date: 26 Sep 88 Prot No.: 88-30		Status: Ongoing
Title: Effects of Carbicarb versus Bicarbonate Alkalinization in the Treatment of Metabolic Acidosis		
Start Date: Oct 88		Est Comp Date: Jul 1990
Principal Investigator(s) Richard F. Kucera, M.D., MAJ, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Medicine/Pulmonary, Critical Care		Associate Investigators: Giles F. Filley, M.D., Webb-Waring Lung Inst Univ Colorado Joseph I. Shapiro, M.D., Univ Colorado, Renal Div
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To compare Carbicarb with 1 M $NaHCO_3$ in the treatment of metabolic acidosis.

Technical Approach: The study will be double blinded with the sequence of drugs being arranged per latin squares. Each patient will be his own control. Each patient will receive one dose of each alkalinizing agent separated in time by approximately 15 minutes. With data being collected at 0, 2, 5, 10, and 15 minutes. The data collected will include pHa, pHv, $PaCO_2$, $PvCO_2$, PaO_2, $PvCO_2$, Hct, Hb, Mean arterial pressure, cardiac output, lactic acid level, Na, HCO_3, K, Xl, PCWP, PAS and PAD.

Number of subjects enrolled to date: 0
Number of subjects enrolled during reporting period: 0

Progress: Study not yet implemented.

Detail Summary Sheet

Date: 28 Sep 88 Prot No.: 88-32		Status: Ongoing
Title: Assessment of Possible Nephrotoxicity of Oral Low-Dose Methotrexate in Treatment of Rheumatoid Arthritis Using Adenosine Deaminase Binding Protein		
Start Date: Aug 88		Est Comp Date:
Principal Investigator(s) David P. Tietjen, MD, MAJ, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Medicine/Nephrology		Associate Investigators: Robert Cameron, MD, MAJ, MC
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: Attempt to identify if there is a rise in adenosine deaminase binding protein (ABP) excretion immediately after the ingestion of a standard dose of oral methotrexate (MTX) as given to rheumatoid arthritis (RA) patients.

Technical Approach: Each patient will collect three urine specimens at home, the first just prior to taking their MTX for the week, the second the next morning, and the third the morning after that. These specimens will be store under refrigeration at home until the next clinic visit when they will be submitted for analysis. Each patient will be asked to do this twice.

Number of subjects enrolled to date: 0
Number of subjects enrolled for the reporting period: 0

Progress: Study is still in preparatory phase, local approval in late FY 88.

Detail Summary Sheet

Date: 28 Sep 88 Prot No.: 88-33		Status: Ongoing
Title: Assessment of Subclinical Contrast Nephropathy Using Urinary Adenosine Deaminase Binding Protein		
Start Date: Aug 88		Est Comp Date:
Principal Investigator(s) David P. Tietjen, MD, MAJ, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Medicine/Nephrology		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: Attempt to determine if the urinary adenosine deaminase binding protein (ABP) assay is sensitive enough to detect proximal tubular injury due to contrast dye in a patient receiving an arteriogram, and to correlate any rise in ABP level to the possible rise in serum creatinine.

Technical Approach: The basic plan is to enlist the participation of inpatients at DDEAMC who are to receive an arteriogram of any vessel(s) by the Department of Radiology in their Special Procedures area. Inclusion and diagnostic criteria will be that the patient is already scheduled to receive an arteriogram for any indication (usually attempting to identify atherosclerotic peripheral vascular disease); that they are willing to volunteer for the study; and that they have had a recent serum creatinine performed (which is required by the Radiology Department prior to the study). All prior evaluations will be done by the admitting service (Medicine, Surgery) and these data will be reviewed by an investigator prior to the study.

Number of subjects enrolled to date: 0
Number of subjects enrolled for the reporting period: 0

Progress: Study is still in preparatory phase, local approval in late FY 88.

Detail Summary Sheet

Date: 23 May 88 Prot No.: 84-73		Status: Completed
Title: Transition into Military Nursing: An Evaluation of A Preceptorship Program.		
Start Date: Sep 84		Est Comp Date:
Principal Investigator(s) Bruce C. Allanach, LTC, AN		Facility: Eisenhower Army Medical Center
Dept/Svc: Nursing		Associate Investigators: Bonnie Jennings, MAJ, AN
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: Examine those factors which facilitate the integration of new ANC officers into a hospital nursing milieu. Determine whether locus of control, as well as affective states of anxiety, hostility, and depression are prime factors in the integration of new ANC officers. Develop a protocol which examines whether there are any differences among nurse preceptees within the same preceptorship program who are judged to be a success. The literature reflects that participants in such programs evaluate the programs as successful. Locus of control and multiple affective states may underscore differences in participants evaluation of a program as successful. A preceptorship program is geared to ease transition phenomenal among new nurses who are prone to affective states associated with change such as anxiety, hostility, and depression.

Technical Approach: The data collection for each preceptee occurs over a period of 26 weeks. The plan is evaluation research using a time-series design. The effects of the program will be examined against the goals through a series of measurements during week 1, 4, 8, 9, 13, and 24 after arrival at DDEAMC. These points of time include before the program begins, during the program, and after the program ends. The principal investigator administers the tools.

Subjects enrolled to date: 42
Subjects enrolled for reporting period: 0

Progress: The success of the preceptorship experience lies in how well the preceptors anchor their expectations and evaluation of the neophyte nurse's behavior in reality. Using Caplan's Mental Health Consultative Model, the monitor is able to help the preceptors clarify their expectations and evaluations of the preceptees. This clarity becomes the impetus from which the preceptor is able to guide the preceptee towards negotiation of the crisis of reality shock and assimilation as a competent nurse.

Detail Summary Sheet

Date: 24 Oct 88 Prot No.: 87-34 Status: Completed

Title: Nutrition Education Adherence Trial (NEAT).

Start Date: Mar 87		Est Comp Date: Mar 88
Principal Investigator(s) Patricia Krause, MAJ, SP		Facility: Eisenhower Army Medical Center
Dept/Svc: Nutrition Care Division		Associate Investigators: Holly A. Dieken, R.D.
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: 1. To identify different learner types by using a composite score from two scales; the diabetes locus of control scale and the preference for learning style inventory. 2. To evaluate the degree of regimen adherence attained when different learners are exposed to one of four treatment programs. The education programs are based on degree of structure in education and frequency of reinforcement.

Technical Approach: Patients who meet the screening criteria and consent to participate will complete two evaluation instruments. Instrument scores are used to determine learner type. Patients are then randomized to one of four treatment groups. Patients attend two 2-hour classes on consecutive weeks. All patients attend the same first class then are split into two different classes for the second class. Based on the treatment group, patients follow either a high or low reinforcement program. On the sixth and sixteenth week of the study patients have blood drawn for fasting blood-glucose and glycosylated hemoglobin, patients are also weighed, complete a self-report of adherence, and give a 24 hour dietary recall.

Number of subjects enrolled to date: 5
Number of subjects enrolled during the reporting period:

Progress: The associate investigator conducted the study, she completed the study, graduated and has left the Univ of Tennessee. She did not submit a final report.

Detail Summary Sheet

Date: 12 Oct 88 Prot No.: 84-4 Status: Ongoing

Title: Metastatic Adenocarcinoma of Unknown Primary Site.

Start Date: Nov 83		Est Comp Date: May 90
Principal Investigator(s) Phyllis Brewer Jack A. Horner		Facility: Eisenhower Army Medical Center
Dept/Svc: Pathology Clinical Investigation		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To determine whether or not the primary site of a metastatic adenocarcinoma of unknown origin can be determined with a high degree of accuracy.

Technical Approach: (1) Gathering cases where primary tumor site is unequivocal.
(2) Manpower: Three.
(3) Morphometric measurements will be made on tumors from known primary sites (adenocarcinomas only) to determine if a statistically significant difference in microvillus size can be assigned to the various primary organs.

Progress: An insufficient number of samples have been available during the past year to significantly further this study. An increased effort will be undertaken during FY 89 to fully resume the earlier work.

Detail Summary Sheet

Date: 29 Sep 88 Prot No.: 88-9		Status: Completed
Title: An Evaluation of Two Methodologies to Detect Antinuclear Antibodies (ANA) in Patient Sera: Indirect Fluorescent Antibody (IFA) and Enzyme-Linked Immunosorbent Assay (ELISA)		
Start Date:		Est Comp Date:
Principal Investigator(s) Mark R. Hopton, CPT, MS		Facility: Eisenhower Army Medical Center
Dept/Svc: Pathology		Associate Investigators: Joseph D. Ristroph, LTC, MS Elizabeth L. King Theresa J. LeBlanc
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To evaluate two different techniques used for the detection of antinuclear antibodies in patient sera.

Technical Approach: Patient serum specimens routinely submitted for ANA determination were tested using the current IFA procedure in the laboratory and simultaneously tested by an ELISA method. Two GS-9 Medical Technologists performed testing and principal investigator interpreted results and formulated conclusions for the study. Funding was for the current fiscal year only and was included in the lab budget. A total of 215 specimens were examined and no adverse reactions were reported.

Progress: This study is completed and results with conclusions as follows:

Parameters Examined:

a. Ease of Test Performance: This is a subjective conclusion based on the personnel who performed both test procedures. The ELISA method was easier to perform and to use for training personnel. The IFA method requires extensive expertise and experience to perform test and use fluorescent microscopy.

b. Time Required for Test Performance: This is an objective conclusion as determined by actually timing the length of both test procedures. Included is total time, start to finish, and actual "hands on" time for each test. The ELISA test took longer start to finish, about 3 hours, due to incubation periods. The IFA test time was 2 hours but required longer "hands on" time for personnel to perform.

c. Interpretation of Test Results: There is both an objective, and a subjective conclusion based on the method of data collection for each procedure. Interpretation of ELISA results was objective with positive and negative results determined quantitatively as measured by a spectrophotometer reader. IA results were subjective determined by visual examination of fluorescence in cells. The ELISA results were easier to read as IFA interpretation requires personnel with extensive experience.

88-9 Continued

d. Overall Cost Incurred by Each Method: This is an objective conclusion based on cost analysis to include number of tests per kit, kit cost, equipment and consumable supplies required and expended.

IFA Cost/test = $1.22

Equipment: Fluorescent microscope, MEDCASE item (already in place). More consumable supplies required than ELISA test.

ELISA Cost/test = $0.83

Equipment: Spectrophotometer reader, CEEP item (already in place). ELISA less expensive overall, especially when training is considered, due to less consumable supplies needed or expended.

Detail Summary Sheet

Date: 21 Sep 88 Prot No.: 85-4		Status: Ongoing
Title: Training Laboratory for Neonatal Procedures.		
Start Date:		Est Comp Date:
Principal Investigator(s) Allan Getts, MD, MAJ, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Pediatrics, Clinical Investigation		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To familiarize residents on rotation through the Department of Pediatrics with endotracheal intubation procedures in the newborn.

Technical Approach: Practice placement of endotracheal tubes. Involves two technicians in Clinical Investigation, staff pediatrician and three to five students.

Progress: There has been no training in the past year.

Detail Summary Sheet

Date: 17 Sep 88 Prot No.: 86-16		Status: Completed
Title: Androgen Responsiveness to LHRH Infusion in Adolescent Females with Polycystic Ovarian Syndrome.		
Start Date: Apr 86		Est Comp Date: Sep 88
Principal Investigator(s) Gary L. Francis, M.D., MAJ, MC		Facility:
Dept/Svc: Pediatrics, Clinical Investigation		Associate Investigators: Alan Getts, MD, MAJ, MC James C. McPherson III, PhD Gary Broadnax, MD, COL, MC
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Jul 87 Review Results Continue

Study Objective: To evaluate this effect over 24 hours, with maximal doses of LHRH (100 micrograms), under conditions where ovarian production alone may be studied (dexamethasone suppression), and by including free testosterone levels, to exclude any interference by changing sex steroid binding globulin levels.

Technical Approach: Blood sampling will be taken for androgen levels following the standard LHRH stimulation test. Population will include all adolescent and young adult women referred for evaluation of hirsutism, oligoamenorrhea, or obesity who have given consent.

Number of subjects enrolled to date: 13
Number of subjects enrolled for reporting period: 0

Progress: All samples have been completed, data should be complete no later than 1 Oct 88. Preliminary data suggests dramatic response in free testosterone in females with ovarian cysts or large ovaries.

Detail Summary Sheet

Date: 25 Sep 88 Prot No.: 86-23		Status: Transfer
Title: Androgen Binding and Reductase Activity in Hair Follicles from Hirsute Females.		
Start Date:		Est Comp Date:
Principal Investigator(s) Gary L. Francis, MD, MAJ, MC		Facility: DDEAMC
Dept/Svc: Pediatrics		Associate Investigators: James C. McPherson III, PhD
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To evaluate the potential role of androgen binding and conversion of testosterone to the more potent androgen dihydrotestosterone, in the pathophysiology of hirsutism.

Technical Approach: Female subjects aged 18-40 will have several facial hairs, body hairs, and pubic hairs removed by traction. Adult female and male normal volunteers will have control samples obtained in an identical fashion. Hair follicles will then be assayed for binding of ^{3}H-dihydrotestosterone and conversion of testosterone to dihydrotestosterone. Data will then be analyzed as to: a) correlation with hirsutism scores, b) correlation with age, and c) correlation with specific etiology of hirsutism.

Number of subjects enrolled for reporting period: 0

Progress: ^{3}H-Testosterone just arrived. Too little time left to initiate binding assays at this time. At the investigator's request this study will be transferred to WRAMC.

Detail Summary Sheet

Date: 17 Sep 88 Prot No.: 86-29		Status: Completed
Title: Neonatal Galactorrhea and Biologically Active Prolactin Levels.		
Start Date:		Est Comp Date:
Principal Investigator(s) Gary L. Francis, MD, MAJ, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Pediatrics, Family Practice, Clinical Inv		Associate Investigators:
Key Words:		James C. McPherson III, PhD William H. Hoffman, MD, MCG
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Jul 87 Review Results Continue

Study Objective: To evaluate the potential role of elevated BA-PRL in the pathogenesis of neonatal galactorrhea and breast engorgement. It will also define a normal range for BA-PRL in human cord blood.

Technical Approach: Infants at birth will have cord blood samples obtained by routine fashion. Samples will be separated and serum frozen for subsequent analysis of PRL by both radioimmunoassay and biological assay. Infants will be examined at the time of their initial discharge, and two-week physical examinations for the presence of galactorrhea as well as breast bud size.

Number of subjects enrolled to date: 57
Number of subjects enrolled for reporting period: 41

Progress: One hundred forty-four newborn infants were examined. Cord blood was obtained from 30 males and 27 females. Data is complete on breast size, galactorrhea, PRL by RIA and BA, progesterone, and pending assays on TSH and T. To date females have larger breasts than males. BA/RIA ratios vary from 0.62 to 2.63 (well above normal adult ratios). All data should be completed by 1 Oct 88.

Detail Summary Sheet

Date: 25 Aug 88 Prot No.: 87-48		Status: Transfer
Title: Biobehavior and Family Psychodynamics in Precocious and Pseudo-orecocious Puberty		
Start Date: Sep 87		Est Comp Date: Sep 89
Principal Investigator(s) Gary L. Francis, MD, MAJ, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Pediatrics Psychiatry & Neurology		Associate Investigators: Peter S. Jensen, MD, MAJ, MC
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To evaluate the frequency and nature of psychological disturbances in patients and parents of patients with precocious puberty, precocious thelarche and precocious adrenarche.

Technical Approach: In addition to the survey, correlations will be made of such disturbances to the diagnosis, the presence and absolute level of gonadotropin and estrogen levels, the presence and absolute level of androgens, the degree of pubertal development, the presence of menarche, and the degree of advancement of bone age.

Number of subjects enrolled to date: 5
Number of subjects enrolled for reporting period: 5

Progress: Five subjects were referred to MAJ Jensen for psychological assessment. Four of the five were felt to be psychologically normal and have only continued to have routine medical followup. The fifth subject was felt to have low self-esteem and has continued to be followed in psychiatry clinic as well. At the investigator's request this study is being transferred to WRAMC.

Detail Summary Sheet

Date: 4 Nov 88 Prot No.: 84-1		Status: Ongoing
Title: The DDEAMC Alcohol Residential Treatment Facility Patient Outcome Study.		
Start Date: Oct 83		Est Comp Date:
Principal Investigator(s) Daniel Hendricks, M.D.		Facility: Eisenhower Army Medical Center
Dept/Svc: Psychiatry and Neurology		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Mar 88 Review Results Continue

Study Objective: To better understand alcoholism and its treatment by assessing some of its biological, psychological, and social concomitants, and determining their diagnostic and prognostic validity.

Technical Approach:

1. Summary of Experimental Design: This study is prospective in design. Measures of the above mentioned variables will be taken prior to, and upon completion of, treatment. Additionally, follow-up questionnaires are to be completed by the patient, spouse, and patient's commander at intervals of twelve months after discharge. Relationships will be measured using analysis of variance and analysis of covariance procedures.

2. Manpower: Personnel required to gather, collate, and interpret the data are, at a minimum, one 91G Behavioral Science Specialist, one Medical Records Technician, and one Clinical Psychologist.

3. Funding: Not applicable.

4. Number of subjects enrolled to date: 140

5. Number of subjects enrolled during reporting period: 0

6. Adverse reactions: None.

Progress: Data analysis continues.

Detail Summary Sheet

Date: 15 Oct 88 Prot No.: 84-28		Status: Ongoing
Title: Reliability and Agreement of Reports of Children's Symptoms.		
Start Date: Apr 84		Est Comp Date:
Principal Investigator(s) Peter S. Jensen, MD, MAJ, MC Stephen N. Xenakis, MD, COL, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Psychiatry-Neurology		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Mar 88 Review Results Continue

Study Objective: To examine the effects of parent and child gender and parental depressive symptoms on the reliability and agreement of children's and parents' reports of children's symptoms and behavior problems.

Technical Approach: (1) One hundred 2-parent families will be selected from on-post housing lists to participate in a study of children's depressive symptoms. To be eligible, families must have a child age 8-12. Also, 100 parents and children who are referred to the Child, Adolescent and Family Psychiatry Service at DDEAMC will also participate in the study. Both groups of families will be compared vis a vis then reports of children's depressive symptoms (Scales used are well-standardized instruments including the Child Behavior Checklist, the Child Depression Inventory, and the Beck Depression Inventory). Reliability and agreement between mother's, father's and children's reports will be analyzed to determine how these indices are affected by sex of parent and child, and depression in the parent.
(2) Manpower required is limited to the two current principal investigators.
(3) Funding required is to provide computer support and statistical analysis.
(4) No adverse reactions.
(5) Subjects enrolled to date: 200
(6) Subjects enrolled for reporting period: 0

Progress: To date, all subjects have been accrued for this study, and data analysis is proceeding. This project has resulted in three publications, with six national presentations. Three more papers are in progress from this work.

Results of the study have demonstrated that parents' reports of children's behavior problems are significantly skewed as a function of parents' own psychiatric symptoms, as well as by environmental variables (family stress, age and sex of child, etc.). These findings were reported in:

Jensen PS, Traylor J, Xenakis SN, Davis H: Child psychopathology rating scales and interrater agreement: I. Parents' gender and psychiatric symptoms. J Am Acad Child Adolesc Psychiatry 1988; 27:442-450.

87-28 Continued

Jensen PS, Davis H, Xenakis SN, DeGroot J: Child psychopathology rating scales and interrater agreement: II. Child and family characteristics. J Am Acad Child Adolesc Psychiatry 1988; 27:451-461.

In addition, a further report of findings about the effects of father absence on children (incidental to the main study) are in press, and will be reported in:

Jensen PS, Grogan DG, Xenakis SN, Bain MW: Father absence: Effects on child and maternal psychopathology. J Am Acad Child Adolesc Psychiatry. (In Press)

Data from this analysis indicated that children may demonstrate increased depression and anxiety, if fathers have been away in the previous year, compared to children whose fathers have not been away. These effects are not obvious to parents and teachers, however.

Detail Summary Sheet

Date: 2 Oct 88 Prot No.: 85-30		Status: Ongoing
Title: Family Risk and Protective Factors: A Prospective Study of Obstetric Patients and Their Families.		
Start Date: Aug 85		Est Comp Date:
Principal Investigator(s) Peter S. Jensen, M.D., MAJ, MC Stephen N. Xenakis, M.D., LTC, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Psychiatry-Neurology/Social Work Service		Associate Investigators: Kent M. Plowman, MD, LTC, MC
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic May 88 Review Results Continue

Study Objective: This study will determine the additive effects of stress, lack of social supports, parental history, parental coping skills, and marital communication on complications of pregnancy in the mother and newborn, and effects of these factors on the child's growth and development.

Technical Approach: One hundred and forty nulliparous women in the first or second trimester of pregnancy and their husbands will be invited to participate in the study. Subjects and spouses will complete surveys to determine their level of social supports, stress, coping skills, marital relationships, etc. These families will be followed prospectively through the course of pregnancy, into the child's first year of life. Statistical analyses will be performed to assess the relationship between interior (stress, supports, coping, etc.) variables and outcome measures (complications of pregnancy, child's growth and development, frequency of illness, etc.).

Number of subjects enrolled to date: 35
Number of subjects enrolled for reporting period: 75

Progress: To date, 100 subjects have been enrolled. A major difficulty with this longitudinal study is subject attrition, however, since many families PCS prior to completion of the study. Data analysis has not yet begun, but it is expected that preliminary analyses will begin in fall 1988. No major problems or adverse patient reactions have been encountered.

Detail Summary Sheet

Date: 3 Oct 88	Prot No.: 87-10	Status: Ongoing

Title: Neuropsychiatric and Psychosocial Aspects of HIV Disease.

Start Date: Oct 87		Est Comp Date:
Principal Investigator(s) Louis Duchin, MD, CPT, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Psychiatry & Neurology		Associate Investigators: Stephen Xenakis, MD, COL, MC Peter S. Jensen, MD, MAJ, MC Fred Tamayo, MAJ, MS
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To evaluate neuropsychiatric/psychosocial/unit functioning of HIV positive soldiers.

Technical Approach: Self report, rater report, neuropsychiatric quesitonnaires/evaluations. No funding or personnel assigned as yet.

Number of subjects enrolled to date: 5
Number of subjects enrolled for reporting period: 5

Progress: Due to lack of support, progress has been slow. Questionnaire packets continue to be assembled by the investigator, and will continue to enroll subjects as time permits.

Detail Summary Sheet

Date: 12 Feb 88 Prot No.: 87-36		Status: Completed
Title: A correlational Study of the MCMI, the MMPI, and the Physician's Psychiatric Diagnosis.		
Start Date: May 87		Est Comp Date: Jan 88
Principal Investigator(s) Sharron K. Schreiber, CPT, MS		Facility: Eisenhower Army Medical Center
Dept/Svc: Psychiatry		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To analyze the relationship between two personality inventories and the physician's psychiatric diagnosis on an inpatient psychiatric ward in a military hospital.

Technical Approach: The study design is a 3 X 3 factorial design using the three most frequently given psychiatric diagnosis, and the three scales on the MCMI and the MMPI which relate most closely to the diagnosis. Data will be grouped and analyzed with correlational statistics. Approximately 120 records will be reviewed. Diagnoses which will be studied are alcohol abuse, schizophrenia and depression.

Number of subjects enrolled to date: 40
Number of subjects enrolled for the reporting period: 40

Progress: This research project was completed in January 1988. Results revealed that upon single scale and total profile analysis there was no difference between the MCMI and the MMPI in regard to their correspondence with the physician's diagnosis on the three diagnoses being studied. A dissertation was written and completed on this project.

Detail Summary Sheet

Date: Nov 88 Prot No.: 87-44		Status: Ongoing
Title: The Relationship Between Coping Resources and Utilization of Medical Services by Military Personnel		
Start Date: Oct 87		Est Comp Date: Dec 88
Principal Investigator(s) Martin L. Seitz, CPT, MS		Facility: Eisenhower Army Medical Center
Dept/Svc: Psychiatry/Psychology		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To determine the ability of the Coping Resources Inventory for Stress (CRIS) to discriminate between high and low users of medical services by active duty personnel.

Technical Approach: Administer three inventories and use this data to predict group membership in high/low users of medical services groups, and normal and abnormal illness behavior groups with use of discrete and linear discriminate analysis.

Number of subjects enrolled to date: 194
Number of subjects enrolled for reporting period: 194

Progress: After finishing data collection at Ft Gordon in October 1987, the investigator attended Officer Basic Course at Ft Sam Houston, graduating in February 1987. Subsequently, he was moved to his current duty station in the MEDDAC, Ft Knox, KY. I have been able to get all my data scored and processed so that soon I hope to be able to analyze the data statistically. Getting the data in a form so that it can be analyzed and deciding on the kind of analyses that need to be done have occupied my efforts up to this point. I plan to complete the project sometime late this coming winter or early spring.

Detail Summary Sheet

Date: 13 Oct 88 Prot No.: 87-45 Status: Ongoing

Title: Child Psychiatric Data Base Project

Start Date: Jul 87	Est Comp Date: Jul 89
Principal Investigator(s) Peter S. Jensen, MD, MAJ, MC Stephen N. Xenakis, MD, COL, MC Alan M. Josephson, MD Perry L. Wolf, MAJ, MS	Facility: Eisenhower Army Medical Center
Dept/Svc: Psychiatry & Neurology, Social Work Svc	Associate Investigators: Don O'Brien, LTC, MS Ms Marilyn Reedy Earl Loomis, MD, MCG Alex Mabe, PhD, MCG Robert C. Ness, PhD, MCG Harry Davis, M.S., MCG R. Adair Blackwood, MD, Charter Hosp Joseph Frey, PhD, MCG
Key Words:	
Accumulative MEDCASE Cost: / Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To facilitate the development of a collaborative data base and computer scoring system of data items completed by parents or the child's main caretaking figures.

Technical Approach: The 94-item data instrument is presently in use in our routine child psychiatric evaluative settings.

Progress: The 94-item data base forms have been received from the printer and are now being implemented into the clinical settings. Progress is underway to develop a computerized program which will scan the forms and enter them into a data base. It is expected that three additional institutions will join in the development of this collaborative data base.

Detail Summary Sheet

Date: 7 Jul 88 Prot No.: 87-50		Status: Completed
Title: Maternal Olfactory Recognition of Infants		
Start Date: Sep 87		Est Comp Date: Jun 88
Principal Investigator(s) Donald W. Grogan, MD, MAJ, MC Peter S. Jensen, MD, MAJ, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Child, Adolescent and Family Psychiatry		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To assess the ability of mothers of newborn infants to recognize their own infants by smell.

Technical Approach: Three infants will be held approximately three to five inches from the mothers' noses, one after the other in random sequence. Each mother will be asked to identify which infant is hers on the basis of smell alone. The results will be analyzed statistically to ascertain if the mothers are able to differentially identify their own infant and to correlate the length of prior exposure with the ability to recognize their own infant.

Number of subjects enrolled to date: 32

Progress: Mothers were given questionnaires assessing the mother's psychological health and her feelings about the pregnancy and the infant. They were then exposed blindfolded and with hearing protection devices to four newborn infants. They were asked to sniff the babies and given three chances to identify which was theirs. Out of a total of 96 tries, there were 34 correct identifications. Mothers of girls recognized their infants no more than would be expected by chance, while mothers of boys recognized their infants twice as frequently. There were no other significant associations, but there were trends which might be related to an effect of smell in mother-infant attachment.

Detail Summary Sheet

Date: 27 Oct 88 Prot No.: 88-16 Status: Completed

Title: Prevalence of Bulimia in Female Army Basic Trainees

Start Date:		Est Comp Date:
Principal Investigator(s) Kelly Palmer, CPT, MC		Facility: Ft Jackson, SC Eisenhower Army Medical Center
Dept/Svc: Psychiatry & Neurology		Associate Investigators: Thomas Jayne, CPT, MC
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: Study design will use a 32-question, anonymous, self-report survey administered to female Army basic trainees. The survey will obtain demographic information and data regarding the frequency and presence of bulimic symptoms and behavior as described in DSM-IIIR.

Technical Approach: A 32-item questionnaire was administered by enlisted staff at the reception station at Fort Jackson to females entering basic training. The questions were designed to make a diagnosis of bulimia using DSM-IIIR criteria. The questionnaire should also be able to distinguish subjects with a current or past diagnosis of anorexia nervosa based on previous medical history, previous lowest weight at present height, and evidence of body image distortions. The identification of anorexia is important as it is listed as an exclusion criteria for the diagnosis of bulimia in both DSM-III and DSM-IIIR.

Number of subjects enrolled during reporting period: 551

Progress: A total of 551 female basic trainees completed our survey. The results were entered on computer. There was a 1.7% incidence of bulimia. Other interesting findings of the study included the different weight reduction strategies endorsed, their frequencies, and preferred strategies according to race. I am in the process of writing a paper suitable for publication, and hope to complete it by December.

Detail Summary Sheet

Date: 25 Oct 88 Prot No.: 87-29		Status: Ongoing
Title: The Effect of Oral Hydration on Bone-to-Soft Tissue Ratios and Subjective Scan Interpretation in Tc 99m Medronate Bone Scans.		
Start Date: Mar 87		Est Comp Date:
Principal Investigator(s) James H. Algeo, Jr. MD, MAJ, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Radiology/Nuclear Medicine Service		Associate Investigators: James A. Green, SGT, CNMT Ruck Davids, SGT, CNMT
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Mar 88 Review Results Continue

Study Objective: To examine the effect of drinking a volume of water after injection for a bone scan and the benefit this might have on the quality of the subsequent images.

Technical Approach: The experiment group will be hydrated 15 minutes following the injection of the radioisotope tracer with one liter of normal tap water under the observation of the medical staff. The water will be ingested over a 45-minute interval. The amount ingested will be recorded for those unable to complete the full amount. The control group will be given the standard instructions to hydrate themselves ad lib. Both experiment and control groups will be scanned approximately four hours following the radioisotope injection.

Number of subjects enrolled to date: 0

Progress: This protocol is still open and has yet to acquire patients. This is because of the departure of the principal investigator in the first year and the reassignment of the new principal to a department chief slot in the second year.

With the return of the principal investigator to less demanding clinical duties, it is anticipated that the protocol can be completed.

Detail Summary Sheet

Date: 28 Oct 88	Prot No.: 78-14	Status: Ongoing

Title: Intraocular Lens Study.

Start Date: May 78		Est Comp Date:
Principal Investigator(s) Keith C. Moses, MD, MAJ, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Surgery/Ophthalmology		Associate Investigators:
Key Words: Intraocular Lens Implant Ophthalmology Aphakia Surgery		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Mar 88 Review Results Continue

Study Objective: Implantation of intraocular lenses in accordance with previously established FDA protocol.

Technical Approach: For the last fiscal year the 3M Style 83 IOL was implanted in 77 successful cases; the Cooper Vision-Cilco Style 523 Kratz IOL was implanted in 15 successful cases. The only implanting surgeon was Keith C. Moses, MAJ, MC, Ophthalmology Service. Funds for current fiscal year have been established within similar parameters as in previous study years. There are 888 cases enrolled in the IOL study to date at DDEAMC Ophthalmology Service. During FY 88, one 3M Style 78 anterior chamber lens was removed due to advancements in posterior lens placement. This 3M Style 78 lens did not malfunction, it was removed and replaced for patient's advantage during another surgical procedure. The IOL was replaced with a 3M Style 83 posterior chamber lens.

Number of subjects enrolled to date: 888
Number of subjects enrolled for reporting period: 82

Progress: FY 88 has been a successful study period with no lens related surgical complications. New published IOL placement techniques were worked into the IOL study program . During study period FY 88, no portion of the IOL Implant Study Program was terminated in the Ophthalmology Service at DDEAMC. The IOL Implant Study Program at Ophthalmology Service, DDEAMC is still in effect, in full.

Detail Summary Sheet

Date: 8 Nov 88 Prot No.: 81-18 Status: Terminated
Title: Environmental Stress and Electromyographic Correlates of Chronic Posterior Trunk Muscle Pain.

Start Date: Feb 81		Est Comp Date:
Principal Investigator(s) Kenneth A. Pettine, MD, CPT, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Clinical Investigation Psychology, Orthopedics		Associate Investigators: Roberto Barja, MD, COL, MC
Key Words: Low back pain Upper back pain Muscle tension		
Accumulative MEDCASE Cost: $19,000	Est Accumulative OMA Cost:	Periodic Mar 87 Review Results Continue

Study Objective: To record those muscles in the posterior trunk of patients with lower and upper back, shoulder, or neck pain related to abnormal muscle tension in order to ascertain relationships between stress, pain, and tension as well as evaluate the effectiveness of muscular relaxation training as a treatment for these problems. The relative effectiveness of these treatments for pain in the above areas with and without underlying muscle tension problems will be evaluated.

Technical Approach: Recordings of muscle tension; objective psychosomatic measures of stress, anxiety, functional locus and other factors; discomfort logs; and other measures will be made before, during and after muscle relaxation treatments of individuals with the problems described above. These progressive measures will be compared with identical measures made of individuals with: 1) musculoskeletal related pain in other areas; 2) high anxiety but no musculoskeletal pain; and 3) posterior trunk pain but no muscle tension problem. A second phase of the study will consist of continuous muscle tension recordings made throughout the day using wearable EMG recorders. These measures will be related to a continuously tape recorded log of environmental loci and stresses.

Number of subjects enrolled to date: 301
Number of subjects enrolled for reporting period: 0

Progress: No further work has been done on this. Terminate at request of investigator.

Detail Summary Sheet

Date: 4 Nov 88 Prot No.: 83-24		Status: Ongoing
Title: Assessment of Vertical Banded Gastroplasty in Treatment of Morbid Obesity.		
Start Date: Apr 83		Est Comp Date:
Principal Investigator(s) Ross S. Davies, M.D., COL, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Surgery Medicine Psychiatry and Neurology		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Mar 88 Review Results Continue

Study Objective: To determine if vertical banded stapling is an effective treatment modality for morbid obesity, to determine its long term effectiveness and complications, and to determine if it will prevent the detrimental effects of morbid obesity.

Technical Approach: Weight loss post bypass will be studied in each patient and compared to average weight loss from other centers following the same procedure. Psychologic testing post-operative will be compared to pre-operative results to examine patient self-image pre and post weight loss.

Subjects enrolled to date: 150
Subjects enrolled for reporting period: 10

Progress: No deaths or significant morbidity. Pouch size has been decreased to 15cc. Additionally, stapling instrument has been changed to a TA-90 instrument that applies four equidistant rows of staples.

Detail Summary Sheet

Date: 3 Oct 88 Prot No.: 83-27		Status: Ongoing
Title: Microsurgery Skill Lab.		
Start Date: Nov 83		Est Comp Date:
Principal Investigator(s) Michael K. Drakeford, MD, CPT, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Surgery/Orthopedic		Associate Investigators: Orthopedic Residents
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Sep 88 Review Results Continue

Study Objective: In depth exposure to the principles and techniques of microsurgery in a laboratory setting - skills developed being transferable to clinical setting - may also stimulate interest in further research related to field of microsurgery.

Technical Approach: Monthly orthopedic rotation in microvascular surgery for residents with special emphasis on microvascular repair of rat femoral arteries. Surgical application: suture of very small vessels and nerves. The project is being done in periods of 30 to 60 days by one resident and one staff.

Progress: Lab work to proceed 17 October 1988 to follow the same protocol of leg perfusion after the suture of the femoral artery and nerve, and surgical technique to suture the femoral nerve. Three residents were trained this past year.

Detail Summary Sheet

Date: 3 Oct 88 Prot No.: 84-25		Status: Ongoing
Title: Comparison of Thermography and Standard Techniques for Detection, Diagnosis and Tracing of Peripheral Vascular Disease and Disorders Marked by Altered Patterns of Peripheral Blood Flow.		
Start Date: Mar 84		Est Comp Date:
Principal Investigator(s) Roberto H. Barja, MD, COL, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Surgery/Orthopedics Clinical Investigation		Associate Investigators: Robert Anderson, MD, LTC, MC Larry Walker, MD, CPT, MC
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To determine the optimal utilization of thermography in clinical evaluation of the vascular status of the affected area. This phase of the project is concentrating on correlating near surface blood flow patterns with reports of pain having varied diagnostic etiologies. The aim is to determine whether thermography is a more sensitive and objective method for initially diagnostic and subsequently tracking pain problems with vascular components than current methods.

Technical Approach: Subjects are recorded thermographically as soon as a patient meeting the eligibility criteria requests treatment. This forms a part of the regular work-up for diagnosis of pain in the Orthopedic Clinic. A series of recordings are made as the patient progresses through treatment and follow-up. The results are then compared with the results of the standard clinical evaluation.

Number of subjects enrolled to date: 329
Number of subjects enrolled for reporting period: 0

Progress: Research on hold until a thermography technician is hired.

Detail Summary Sheet

Date: 15 Oct 88 Prot No.: 85-5		Status: Ongoing
Title: Advanced Trauma Life Support Course.		
Start Date: Jan 85		Est Comp Date:
Principal Investigator(s) Robert Brigham, LTC, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Surgery Clinical Investigation		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Sep 88 Review Results Continue

Study Objective: To provide training for physicians who are not dealing with major trauma on a day-to-day basis, and who may have to evaluate the seriously injured patient during the period immediately after injury. Also, it is intended to provide the basic knowledge and skills necessary to identify those patients whose need is for rapid assessment, resuscitation, and stabilization.

Technical Approach:

a. Design: The Advanced Trauma Life Support Course is a two day training session in which participants are given didactic instruction followed by practical skill stations and an animal lab. Testing is accomplished by a written exam and a practical exercise in which a simulated trauma victim is resuscitated.

b. Manpower: Requirements are as follows:

Course Director (1 MC)
Course Administrator (MS)
Instructors (6 MC)
Logistical Support (2 EM)
Moulage patients (4 EM)

c. Funding: Administrative cost derived from Office of Medical Education.

Progress: During the past year one Advanced Trauma Life Support Instructor Course was conducted (November 1987). This was very successful with the training of 16 new instructors. The animal lab portion of the course proceeded efficiently and was extremely helpful in the training of our students.

Detail Summary Sheet

Date: 22 Apr 88	Prot No.: 86-8	Status: Completed

Title: Ultrasound Evaluation of the Rotator Cuff.

Start Date: Feb 86		Est Comp Date:
Principal Investigator(s) Michael Drakeford, MD, CPT, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Surgery/Orthopedic		Associate Investigators: Michael J. Quinn, MAJ, MC Kenneth A. Pettine, CPT, MC Stephen L. Simpson, CPT, MC
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: Attempt to determine the sensitivity and specificity of ultrasound in diagnosing rotator cuff tears and pathology.

Technical Approach: The experimental design is to compare the diagnostic value of blind noninvasive ultrasound with subsequent arthrogram and arthroscopy in shoulders with symptomatic rotator cuff disease. Additionally, the blind ultrasound studies of the symptomatic shoulders will be compared with the blind ultrasound studies of 50 clinically asymptomatic shoulders in individuals 18-35 years of age.

Manpower involves one radiologist who will do all of the ultrasound studies and four orthopedists who will accomplish the examinations and referrals.

Number of subjects enrolled to date: 90
Number of subjects enrolled for reporting period: 36

Progress: Fifty patients with signs and symptoms of chronic impingement syndrome and/or rotator cuff tear were evaluated with shoulder arthrograms and ultrasonography. Ninety asymptomatic shoulders of a comparable age underwent ultrasonography to serve as a control group. All controls had normal ultrasonograms with no hypoechoic or sonolucent areas. The 50 symptomatic shoulder patients had the following: 28 patients had a normal arthrogram, with either normal ultrasonograms or "buckling" of the supraspinatus tendon on ultrasonography consistent with Stage II impingement syndrome; 8 patients had normal arthrograms but ultrasonography indicated a thin (less than 4mm) irregular supraspinatus tendon indicative of early Stage III impingement; 11 patients had complete rotator cuff tears visualized on both arthrography and ultrasonography, with 9 of these patients undergoing surgery that confirmed complete tears in all; 2 patients had a false positive sonogram; and 1 patient had a false negative sonogram. Thus, the ultrasonography's overall accuracy rate was 94%. We have found real time ultrasonography to be a diagnostically sensitive and specific noninvasive method to evaluate patients with shoulder impingement syndrome, leading us to recommend it as a primary imaging technique to obviate or supplement arthrography in evaluating rotator cuff disease.

Detail Summary Sheet

Date: 20 Jun 88 Prot No.: 87-6		Status: Completed
Title: Postoperative Analgesia After the Addition of Morphine or Hydramorphone to Intrathecal Tetracaine for Total Joint Surgery.		
Start Date: Dec 86		Est Comp Date: Nov 87
Principal Investigator(s) G. Lee Brookshire, MD, MAJ, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Surgery/Anesthesia & Operative Service		Associate Investigators: Thomas W. Overly, CPT, AN Frank R. Ebert, MAJ, MC Kenneth A. Pettine, MAJ, MC
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Mar 88 Review Results Continue

Study Objective: To determine if intrathecal opiates provide for better postoperative pain relief and hence shorter hospitalization, fewer complication rates, and better orthopedic outcomes.

Technical Approach: Patients will be enrolled into one of three groups. The first group will receive the usual spinal anesthetic with tetracaine and receive IV and IM narcotics postoperatively. The second group will receive the tetracaine spinal anesthetic with dilaudid added. Their postoperative pain will also be managed with IV and IM narcotics. The third group will receive the usual tetracaine spinal anesthetic with duramorph added. Again, their postoperative pain will be managed by IV and IM narcotics. All patients will then spend the first postoperative day in the SICU. Once they are stable, patients will spend the remainder of their hospitalization on the ward.

Number of subjects enrolled to date: 60
Number of subjects enrolled during reporting period: 1

Progress: A total of 60 patients were examined. All data collection is complete and the statistics have been performerd. Currently the paper is being written and will be submitted for publication. CPT Pettine will continue with this phase.

Detail Summary Sheet

Date: 4 Nov 88 Prot No.: 87-8 Status: Terminated
Title: Serum Creatine Kinase and the Acute Abdomen.

Start Date:		Est Comp Date:
Principal Investigator(s) Robert W. Brigham, MD, COL, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Surgery		Associate Investigators:
Key Words:		Ross S. Davies, MD, COL, MC James Hancock, MD, CPT, MC
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To analyze a series of patients with acute surgical abdomens and correlate the findings at operation with preoperative creatine kinase serum isoenzyme levels. To determine if such correlation may provide additional presumptive diagnostic information as to the viability of the bowel. To examine the relationship in ratio of lactice dehydrogenase (LSH) isoenzymes and creatine (CK) isoenzymes during the same preoperative period in individuals with mesenteric infarction, bowel obstruction and other acute surgical emergencies.

Technical Approach: Patients will have their blood drawn as part of the normal preoperative laboratory evaluation and again 24 hours postoperatively. The patients' blood will be analyzed for the total creatine kinase (CK), percent of each CK isoenzyme, total lactate dehydrogenase (LD), and percent of each LD isoenzyme.

Number of subjects enrolled to date: 6
Number of subjects enrolled for reporting period: 0

Progress: No further work done on this study. Terminate.

Detail Summary Sheet

Date: 14 Sep 88	Prot No.: 87-9	Status: Ongoing
Title: Iontophoresis of Steroids: Does it Affect Rabbit Tendon Strength.		
Start Date: May 87		Est Comp Date:
Principal Investigator(s) Paul J. Herzwurm, MD, CPT, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Surgery/Clinical Investigation		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Sep 88 Review Results Continue

Study Objective: To study the effect of iontophoresis of steroids on rabbit tendon strength.

Technical Approach: The study was performed last May but we ran into technical difficulties in clamping the tendons when testing their tensile strength.

Progress: Chief, Orthopedic Service has become involved and is currently working with an individual who will develop a proper clamp to hold the tendons.

Detail Summary Sheet

Date: 3 Oct 88 Prot No.: 87-13		Status: Ongoing
Title: Enhancement Video Endoscopy: Preliminary Assessment of Digital Enhancement.		
Start Date:		Est Comp Date:
Principal Investigator(s) Stephen M. Gooden, MD, LTC, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Surgery, Clinical Investigation		Associate Investigators: Roosevelt J. Stallings, MD, LTC, MC
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To perform initial assessment of various methods of enhancing and electron cally analyzing video images of the gastrointestinal tract in both normal dogs and dogs with surgically created pathology,

Technical Approach: The experiment is designed to perform standard video endoscopic procedures and to enhance the image either directly during the procedure or later from the video tape recording utilizing various methods of computer and video electronic image processing.

Progress: Since the initiation of the study, much data has been gathered which has aided in the development of improved endoscopic techniques by our service. Two papers have been written as evidence of that study. Data tinues to be collected to further improve our endoscopic image.con

Detail Summary Sheet

Date: 1 Oct 87 Prot No.: 87-30		Status: Completed
Title: A Comparison of Labetalol and Sodium Nitroprusside in Postoperative Patients Undergoing Carotid Endarterectomy.		
Start Date: Mar 87		Est Comp Date: Mar 88
Principal Investigator(s) Daniel J. Geniton, CRNA, CPT, AN		Facility: Eisenhower Army Medical Center
Dept/Svc: Surgery/Anesthesia & Operative Service		Associate Investigators: G. Lee Brookshire, MD, MAJ, MC
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To assess if labetalol is as effective as nitroprusside in controlling postoperative hypertension in carotid endarterectomy.

Technical Approach: Subjects are randomized into two groups, given a standard anesthetic protocol, and are given either labetalol or nipride when they achieve a target blood pressure. Data (systolic, diastolic, and mean BP) is then recorded for 12 hours while the subject is in SICU. There are no funding or manpower considerations at this point. There have been no adverse reactions to treatment in any subject to date.

Number of subjects enrolled to date: 19
Number of subjects enrolled during reporting period: 7

Progress: All data collection and analysis are completed. The paper was published at MCG as a thesis paper and is now being sent to the anesthesia literature for publication.

Detail Summary Sheet

Date: 3 Oct 88	Prot No.: 87-35	Status: Completed
Title: Omental Splenic Autotransplantation: Optimal Transplant Size for Maximal Protective Effect Against Pneumococcal Bacteremia.		
Start Date: Mar 87		Est Comp Date:
Principal Investigator(s) Edward McWhirt, MD, CPT, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Surgery/Clinical Investigation		Associate Investigators: Edward R. Setser, MD, CPT, MC Robert A. Brigham, MD, LTC, MC Ross S. Davies, MD, COL, MC
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To compare five quantities of splenic tissue autotransplantation in order to establish the optimal splenic transplant for the maximal protective effect against a challenge of Streptococcus pneumoniae using LD-50 determinations for each percentage group of the experimental animals.

Technical Approach: After its removal, the spleen will be diced into small 1mm x 2mm x 2mm pieces. Autotransplantation will consist of 20%, 40%, 60%, 80% and 100% of the spleen transplanted in an omental pocket. A culture of Streptococcus pneumoniae type I will be used for inoculation. Organisms will be passed through a rat multiple times to ensure encapsulation prior to challenge. Serotype will be confirmed by type I specific antisera and india ink preparations will be used to check for the presence of a capsule.

Progress: Study completed. Data being analyzed.

Detail Summary Sheet

Date: 20 Jun 88 Prot No.: 87-47		Status: Completed
Title: Evaluation of Plasma Catecholamines in Patients Undergoing General Anesthesia for Surgical Procedures		
Start Date: Sep 87		Est Comp Date: Nov 87
Principal Investigator(s) Alan S. Black, MD, CPT, MC G. Lee Brookshire, MD, MAJ, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Surgery/Anesthesiology & Operative Svc		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To evaluate the role of epinephrine on memory and learning during anesthesia.

Technical Approach: Blood will be drawn for plsma catecholamine assay immediately prior to induction, immediately after induction, post-intubation, post surgical skin incision, then every half hour until the conclusion of the case.

Number of subjects enrolled to date: 14
Number of subjects enrolled for reporting period: 14

Progress: This study was a collaborative effort with MCG, data collected from our subjects was sent to MCG. The investigator at MCG will be writing a paper for presentation later this year. The study is completed.

Detail Summary Sheet

Date: 3 Oct 88 Prot No.: 87-52		Status: Ongoing
Title: The Richards II Series Total Hip Prosthesis: A Clinical Review with a Minimum 2-year Follow-up Evaluation		
Start Date: Oct 87		Est Comp Date: Mar 89
Principal Investigator(s) David A. Volgas, CPT, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Surgery/Orthopedic Service		Associate Investigators: Frank C. Ebert, MAJ, MC Harvey Montijo, CPT, MC Roberto H. Barja, COL, MC
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To determine the long-term (2 years or greater) clinical failure rate of the Richards Series II total hip prosthesis.

Technical Approach: The study will include a chart review and a routine follow-up physical and radiographic examination by one of the investigators as well as a patient questionnaire.

Number of subjects enrolled to date: 55
Number of subjects for reporting period: 55

Progress: All 55 patients were interviewed and their old and new x-rays reviewed for evaluation and assessment of their activity level and the biomechanical status of their artificial joints.

Detail Summary Sheet

Date: 20 Jun 88 Prot No.: 87-54		Status: Terminated
Title: The Effect of Position and Supplemental Oxygen on Arterial Oxygen Saturation During Transport to the Post-Anesthesia Care Unit		
Start Date: Oct 87		Est Comp Date: Jan 88
Principal Investigator(s) Daniel J. Geniton, CPT, AN		Facility: Eisenhower Army Medical Center
Dept/Svc: Surgery/Anesthesia & Operative Service		Associate Investigators: G. Lee Brookshire, MD, MAJ, MC
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To determine the effect of three transport positions on arterial oxygen saturation during transport to post-anesthesia care unit and to examine the efect of providing supplemental oxygen to patients during transport to post-anesthesia care unit.

Technical Approach: Subjects will be randomized into one of six groups and have pulse oximetric determination of SaO_2 recorded.

Number of subjects enrolled: None.

Progress: Study was not implemented due to lack of time and no interest in performing it by the remaining staff.

Detail Summary Sheet

Date: 1 Oct 88 Prot No.: 87-55		Status: Ongoing
Title: An Evaluation of the Effects of Hearing Protective Devices on Speech Recognition Performance in Noise of Hearing-Impaired Listeners		
Start Date: Oct 87		Est Comp Date: May 90
Principal Investigator(s) Graham L. Wilde, MAJ, MS		Facility: Eisenhower Army Medical Center
Dept/Svc: Surgery/Audiology		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To investigate the effects of hearing protection on speech recognition performance of listeners with mild to moderate high frequency, noise induced hearing loss.

Technical Approach: Subjects will be tested without hearing protection and while wearing each of the hearing protectors in a background of speech-shaped noise. The speech noise is similar in spectral shape to the competing noises commonly found in everyday situations. The test material will consist of test items from the revised Speech Perception In Noise (SPIN) test.

Number of subjects enrolled to date: 19.
Number of subjects enrolled during the reporting period: 19.

Progress: As of September 1988 19 of the 36 subjects required to complete the study have been evaluated. Time constraints and difficulty obtaining hearing impaired subjects have caused the delay in study completion.

Detail Summary Sheet

Date: 8 Nov 88	Prot No.: 88-1	Status: Completed
Title: A Prospective Random Study to Compare the Efficacy of Voltaren vs Marketed NSAID in the Treatment of Osteoarthritis		
Start Date: Nov 87		Est Comp Date:
Principal Investigator(s) Kenneth A. Pettine, M.D., CPT, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Surgery/Orthopedics		Associate Investigators: Roberto H. Barja, M.D., COL, MC
Key Words:		Frank R. Ebert, M.D., MAJ, MC
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To evaluate the safety of selected marketed NSAIDs in patients with osteoarthritis.

Technical Approach:

Number of subjects enrolled to date: 12
Number of subjects enrolled during reporting period: 12

Progress: Study has been completed. All information sent to CIBA-GEIGY.

Detail Summary Sheet

Date: 12 Sep 88 Prot No.: 88-5		Status: Ongoing
Title: Investigation of Cryotreatment on the Epiphysis of Growing Rabbit Bones.		
Start Date:		Est Comp Date:
Principal Investigator(s) Harvey Montijo, MD, CPT, MC James S. St. Louis, MD, CPT, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Surgery/Orthopedic		Associate Investigators:
Key Words:		Roberto Barja, MD, COL, MC Michael Tidwell, MD, MAJ, MC
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic 8 Sep 88 Review Results Continue

Study Objective: 1) To evaluate cryotherapy times on the epiphysis of 6 week old rabbits (right femur); 2) to examine both grossly and microscopically, the effects of cryotherapy on bone growth epiphyseal closure.

Technical Approach: A cryoprobe after surgical cut-down is applied to epiphyses in the distal right femur of 6 week old rabbits. Four weeks post-cryotreatment the rabbits are euthanized, then a surgical cut-down is performed to remove the right and left femur. The pathologist then determines the gross effect on growth plates and any deformities present on the right vs the left femur. Microscopic specimens of the cryotreated epiphyses are examined to evaluate remaining potential for growth, microvascular structures, and uniformity of cryological effects.

Progress: Preliminary reports indicate that cryotherapy has only minimally affected some of the epiphysis. We are considering using a smaller cryoprobe to try to stunt the growth plate.

Detail Summary Sheet

Date: 9 Nov 88 Prot No.: 88-6		Status: Ongoing
Title: Distal Thigh Pain and Stress Tranfer in Uncemented Total Hip Arthroplasties. A Scintigraphic Analysis.		
Start Date:		Est Comp Date:
Principal Investigator(s) Stephen L. Simpson, MD, CPT, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Surgery/Orthopedic		Associate Investigators: Frank R. Ebert, MD, MAJ, MC James H. Algeo, Jr., MD, MAJ, MC Kenneth A. Pettine, MD, MAJ, MC
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To determine if anterior thigh pain in uncemented total hip arthroplasties is caused by distal stress transfer through the femor prosthesis.

Technical Approach: Routine bone scans will be done at various time intervals following cemented and uncemented total hip arthroplasties. The bone scan is an accepted method of evaluating hip prostheses, having demonstrated both prospectively and retrospectively excellent sensitivity and good specificity in detecting and defining abnormalities such as loosening, fracture, and infection.

Number of subjects enrolled to date: 30
Number of subjects enrolled for reporting period: 30

Progress: Out of 30 patients, 10 have come in for 6 months checkup, the others are at between 0 and 6 months. Need to enroll another 30 patients for total follow up of one year. There have been no adverse effects or problems.

Detail Summary Sheet

Date: 20 Jun 88 Prot No.: 88-17 Status: Terminated

Title: The Use of Intrapleural Catheters in the Management of Post Cholecystectomy Pain

Start Date:		Est Comp Date:
Principal Investigator(s) Abe T. Haliczer, M.D.		Facility: Eisenhower Army Medical Center
Dept/Svc: Surgery/Anesthesia & Operative Svc		Associate Investigators: G. Lee Brookshire, MD, MAJ, MC Daniel S. Rowe, MD
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To determine whether local anesthetics administered via an intrapleural catheter is a superior method of postoperative analgesia when compared to systemically administered narcotics. To assess the risk:Benefit ratio of both analgesic techniques by assessing quality of analgesia, duration, pulmonary function status, side effects, and complications.

Technical Approach:

Number of subjects enrolled during reporting period: None.

Progress: Study was not implemented due to lack of time and no interest in performing it by the remaining staff.

Detail Summary Sheet

Date: 27 Sep 88 Prot No.: 88-34 Status: Ongoing

Title: Stress Radiography in the Detection of Shoulder Instability

Start Date:		Est Comp Date:
Principal Investigator(s) Stephen L. Simpson, MD, CPT, MC Kenneth A. Pettine, MD, MAJ, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Surgery/Orthopedic Service		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: Stress radiography is an attempt to demonstrate abnormal motion of the glenohumeral joint, which may be done in the office setting and does not require the administration of an anesthetic. The purpose of this study is to perform a modified technique of stress radiography in several subgroups: 1) healthy volunteers without history of shoulder problems, 2) patients with generalized ligamentous laxity and shoulder pain, and 3) patients with traumatic glenohumeral subluxation and/or dislocation.

Technical Approach:

Progress: Study in preparation, local approval in late FY 88.

Detail Summary Sheet

Date: 24 Oct 88 Prot No.: 78-14		Status: Ongoing
Title: Intraocular Lens Study.		
Start Date: Nov 80		Est Comp Date:
Principal Investigator(s) William C. Lloyd, MD, MAJ, MC		Facility: USA MEDDAC, Ft Benning, GA
Dept/Svc: Surgery/Ophthalmology		Associate Investigators: Mary A. O'Hara, MD, MAJ, MC
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Mar 88 Review Results Continue

Study Objective: Provide data to support FDA approval for marketing intraocular devices.

Technical Approach: Surgical insertion of intraocular lens. Presently, intraocular lenses selected for implantation include IOLAD Model G108B, 3M Vision Care Style 83, Precision-Cosmet Model 8201, and Cilco Styles SK21VO, SAC5VO.

Number of subjects enrolled to date: 506
Number of subjects enrolled for reporting period: 100

Progress: All lenses are FDA approved; case registration performed as part of adjunct safety study.

Detail Summary Sheet

Date: 24 Oct 88 Prot No.: 86-26		Status: Ongoing
Title: A Randomized, Controlled Trial of Initially Treated Corneal Abrasions: Physician Mandated Every 24 Hours Follow-Up Versus Patient Initiated (PRN) Follow-Up.		
Start Date: Jul 86		Est Comp Date:
Principal Investigator(s) Ted D. Epperly, MD, MAJ, MC		Facility: USAMEDDAC, Ft Benning, GA
Dept/Svc: Family Practice		Associate Investigators: Mark A. Connelly, MD, MAJ, MC Steven E. Reissman, DO, MAJ, MC Frank Celestino, MD, Bowman Gray School of Med, Winston Salem, SC
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To determine if patients need to be checked on a daily basis for healing of their corneal abrasion versus a PRN approach to follow-up if symptoms/signs develop.

Technical Approach: This study will be a randomized, prospective controlled trial involving patients with uncomplicated corneal abrasions. A full eye exam will be done on all patients and all patients will then be treated in a standardized fashion. Patients will then be randomized into two groups for follow-up: Group 1 will receive daily follow-up and reexamination until healing is documented (negative flourescein) and symptoms are gone. Group 2 will be instructed to leave patch on for 36 hours and then remove. Upon patch removal, follow-up will be PRN and patient-initiated based on the patient's perception of persistent bothersome symptoms. Data will be analyzed using the chi-squared methodology for dichotomous variables. The measured outcome variables will be number of re-visits, complications, and days of symptoms in each group.

Number of subjects enrolled to date: 0
Number of subjects enrolled for reporting period: 0

Progress: Due to other commitments, study has not been started.

Detail Summary Sheet

Date: 24 Oct 88 Prot No.: 86-27 Status: Terminated
Title: The Effect of the Internship on Fitness

Start Date: Jun 86		Est Comp Date: Jul 88
Principal Investigator(s) John M. Henderson, DO, MAJ, MC		Facility: USAMEDDAC, Ft Benning, GA
Dept/Svc: Family Practice		Associate Investigators: W. Jefferson Berry, MD, CPT, MC James E. Mace, COL, IN
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To assess a change in physiologic parameters during the internship year.

Technical Approach:

1. Assess several parameters of fitness prior to beginning duty in the PGY-1, prior to 1 July 1986.

2. Reassess these parameters 6 months into the PGY-1, and again 12 months into the PGY-1.

3. Compare each individual's performance against their earlier findings, against their confreres and against an age-matched national mean for the Army and the general civilian population.

Number of subjects enrolled to date: 9
Number of subjects enrolled for reporting period: 0

Progress: Subjects completed their indentured internment. Project trashed because subjects increased their fitness while being studied.

Detail Summary Sheet

Date: 24 Oct 88	Prot No.: 87-41	Status: Ongoing

Title: An Exploration of the Relationship Between Client Expectations and the Working Alliance

Start Date: 30 Sep 87		Est Comp Date: Jan 89
Principal Investigator(s) Scott S. Jones, M.A.		Facility: USAMEDDAC, Ft Benning, GA
Dept/Svc: Social Work Services/Psychiatry Services		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To measure the shape and strength of the relationship between the expectations about counseling held by individual adult outpatients who are entering counseling for teh first time and the working alliance developed between the individuals and their counselors. The study will also examine: 1) which types of expectations best predict the working alliance, 2) whether initial expectations about counseling differ significantly from initial preferences, 3) if such difference exists, whether expectations or preferences best predict the working alliance, and 4) what effect disconfirmation of client expectations or preferences has on the status of working alliance.

Technical Approach: The experimental design of the study is correlational. Subjects are informed of the nature of the study prior to consenting to participate. Subjects fill out questionnaires defining their expectations of counseling before the first counseling session. Following the third counseling seession subjects fill out questionnaires defining their relationship with their counselors. Data from the questionnaires are correlated to define the shape and strength of the working or therapeutic reliance.

Manpower: Counselors from Alcohol and Drug Services are used as counselors for the study.

Number of subjects enrolled to date: 40
Number of subjects enrolled for reporting period: 40

Progress: All data has been collected. Results have not been analyzed. Target date for total completion of project is 1 January 1989.

Detail Summary Sheet

Date: 24 Oct 88 Prot No.: 87-56		Status: Ongoing
Title: Comparison of Psyllium Plantago and Xanthan Gum in the Dietary Management of Diabetes Mellitus		
Start Date: Sep 87		Est Comp Date: Mar 89
Principal Investigator(s) John D. Cowsar, DO, MAJ, MC		Facility: USA MEDDAC, Fort Benning, GA
Dept/Svc: Family Practice Community Medicine		Associate Investigators: Donn Richards, MD, CPT, MC Carol Handley, MAJ, MS
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To demonstrate that feeding psyllium plantago mucilloid and xanthan food gum can effectively improve glucose intolerance in patients with non-insulin dependent diabetes.

Technical Approach: Psyllium plantago mucilloid fiber (12 gm/day) and xanthan good gum (12 gm/day) will be administered for 6 week intervals in a double blind, placebo cross-over design to determine which fiber is more effective in improving glucose tolerance and lowering cholesterol and triglyceride levels. There will be a 3 week washout period between the test periods. Forty-eight adult subjects with non-insulin dependent diabetes mellitus having elevated fasting blood glucose within the range of 150-250 mg/dl will comprise the test group. The test subjects will serve as their own controls. Fasting, 1, and 2 hour post 75 gm oral glucose challenge serum glucose and insulin measurements will be obtained at the start of the study, and at the end of the test and placebo periods. Fasting total cholesterol, HDL fraction, and triglycerides will be measured at the beginning of the study and after 6 weeks of each study period. A questionnaire will be administered to evaluate side effects. A 3 day diet diary will be obtained prior to the study and during each test period to estimate the carbohydrate, protein, fat, and nonabsorbable fiber content. Laboratory results will be analyzed to confirm the presence of a significant clinical effect of these two viscous fiber analogues in terms of their ability to improve glucose tolerance and lower cholesterol and triglyceride levels in an inert placebo. A comparison will also be made between psyllium and xanthan gum to determine if there is a significant difference in their individual efficacy.

Number of subjects enrolled to date: 12
Number of subjects enrolled for reporting period: 12

Progress: Due to the associate investigator being TDY to the Reforger exercise in Europe, the study has been delayed temporarily, however, it is still ongoing. We have already completed data on 12 patients.

Detail Summary Sheet

Date: 24 Oct 88 Prot No.: 87-57		Status: Ongoing
Title: The Relationship Between Airborne Activities and Knee Pain		
Start Date: Sep 87		Est Comp Date:
Principal Investigator(s) John M. Henderson, MD, MAJ, MC		Facility: USA MEDDAC, Fort Benning, GA
Dept/Svc: Family Practice Community Medicine		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: The common presentation of anterior knee pain syndromes in airborne soldiers has prompted investigation into the stress placed on the extensor mechanism of the knee from airborne activities versus other non-airborne soldierly activities. This study compares the knee profiles of both airborne and non-airborne soldiers.

Technical Approach: The knee profiles consist of demographic, historical, clinical, and radiographic information that is matched concurrently by age, occupation, time in service, miles run per week, and current sports activities.

Progress: Due to prior commitments, study has not been started.

Detail Summary Sheet

Date: 13 Oct 87 Prot No.: 87-58		Status: Ongoing
Title: Quantifying the Ranger Experience: The Clinical Aspects of Elite Military Training and Over-training		
Start Date: Sep 87		Est Comp Date:
Principal Investigator(s) John M. Henderson, DO, MAJ, MC		Facility: USA MEDDAC, Ft Benning, GA
Dept/Svc: Family Practice Community Medicine		Associate Investigators: W. Jefferson Berry, CPT, MC James E. Mace, COL, IN
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To investigate the effect of training, induced changes in anthropometric and physiologic parameters on psychologic affect and general fitness parameters.

Technical Approach: Anthropometric, physiologic, psychologic, and general fitness measurements will be followed through Phase 1 of Ranger School.

Number of subjects enrolled to date: 11

Progress: Eleven subjects studied, analysis proceeding but as yet unfinished. Preliminary report nearing completion. Followup study is approved but lacks funding.

Detail Summary Sheet

Date: 24 Oct 88 Prot No.: 87-59		Status: Ongoing
Title: Core Temperatures in Soldiers During Routine Physical Training		
Start Date: Sep 87		Est Comp Date: Dec 88
Principal Investigator(s) W. Jeff Berry II, MD, CPT, MC		Facility: USA MEDDAC, Ft Benning, GA
Dept/Svc: Family Practice Community Medicine		Associate Investigators: John M. Henderson, DO, MAJ, MC
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To describe the physiologic response to training in the heat at the Infantry Training Center.

Technical Approach: Phase one is a prospective description of a pilot nature for Phase two. During this phase the wet bulb globe temperature index and associated heat category will be noted, and the core temperatures of the subjects will be measured at the time of exercise. Prior to exercise, the subjects will be screened to assess 1) their risk of sustaining heat injury, and 2) their aerobic fitness. The subjects will be physicians and the mode of exertion will be their self prescribed training regimens of running on a paved road. After the exercise, the subjects will record their self perceived exertion scale and their self perceived heat category. Phase two is a similar project except that the subjects will be a company of Rangers. The same screening and post exertion self assessments will be made. Core temperatures will be measured by a thermistor passed to a point 15 cm beyond the anal sphincter. WBGT will be measured by metorological services at Lawson Airfield.

Number of subjects enrolled to date: 8

Progress: The study group was changed at the request of the School Brigade and the Airborne School. The subjects used were 8 students from the 1/507th Co C. The group had their temperatures monitored during exercise and during cooling. Comparisons were made between rate of cooling with and without water showers. Analysis still pending.

Detail Summary Sheet

Date: 24 Oct 88 Prot No.: 87-60 Status: Completed
Title: Care Seeking Behavior After a Mass Casualty Episode

Start Date: Sep 87		Est Comp Date: Dec 87
Principal Investigator(s) Victor G. McGlaughlin, Jr, CPT, MC		Facility: USA MEDDAC, Ft Benning, GA
Dept/Svc: Family Practice Community Medicine		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To determine changes in care seeking behavior in soldiers involved in a mass casualty episode compared with a control group.

Technical Approach: Two questionnaires were administered to 28 soldiers in accident and 130 controls (IBQ & Spielberger State-Trait).

Number of subjects enrolled to date: 158

Progress: Those soldiers treated for injuries as inpatients or outpatients and the controls were compared using analysis of variance methods. No significant differences in care seeking behavior (in terms of the dimensions of illness behavior, state or trait anxiety, or use of sick call) were found between these three groups.

Detail Summary Sheet

Date: 27 Oct 88	Prot No.: 78-14	Status: Ongoing

Title: Intraocular Lens Study.

Start Date: Oct 81		Est Comp Date:
Principal Investigator(s) Robert A. Breffeilh, MD, MAJ, MC		Facility: USA MEDDAC, Ft Campbell, KY
Dept/Svc: Surgery/Ophthalmology		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To provide to cataract patients the latest development in ophthalmic surgery concerning the correction of surgical aphakia.

Technical Approach: Extracapsular cataract extraction followed by the implantation of an intraocular lens implant.

Funding was solely from clinic operating budget.

Types of lenses being used:

a. American Medical Optics, Mdl PC11B Modified C Loop posterior chamber lens.
b. IOLAB, Mdl 85J, One-piece anterior chamber lens.
c. Optical Radiation, Mdl UV40A4 Modified C Loop posterior chamber lens.
d. Surgidev Mdl B2024 Modified C Loop posterior lens.
e. Storz Mdl MC10 Modified C Loop posterior lens.

Cost per lens: from $125 to $375 each.

Subjects enrolled to date: 131
Subjects enrolled for the reporting period: 0

Progress: No investigational lenses were implanted during the reporting period.

Detail Summary Sheet

Date: 27 Sep 88 Prot No.: 88-35		Status: Ongoing
Title: A Comparison of Hydrocortisone Phonophoresis Using Pulsed versus Continuous Ulstrasound for the Treatment of Lateral Epicondylitis		
Start Date: Sep 88		Est Comp Date:
Principal Investigator(s) Barry L. Karalfa, CPT, SP		Facility: USA MEDDAC, Ft Campbell, KY
Dept/Svc: Surgery/ Physical Therapy Clinic		Associate Investigators: Francis J. Pottenger, CPT, SP
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To evaluate the clinical use of HCP in the treatment of lateral epicondylitis; to evaluate differences in the clinical effectiveness of HCP delivered with continuous and pulsed ultrasound; and to provide further validation or invalidate the use of the McGill Pain Questionnaire for lateral epicondylitis through correlation with quantitative strength data.

Technical Approach:

Progress: Study in preparation, local approval in late FY 88.

Detail Summary Sheet

Date: 7 Oct 88	Prot No.: 78-14	Status: Terminate

Title: Intraocular Lens Study.

Start Date: Jul 81		Est Comp Date:
Principal Investigator(s) Milne, Henry L, M.D., MAJ, MC		Facility: USA MEDDAC, Ft Jackson, SC
Dept/Svc: Surgery/Ophthalmology		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: Insertion in selected patients of Tennant Anterior Chamber Anchor Lens.

Technical Approach: Using routine intracapsular cataract techniques, the lens would be inserted prior to final closure of the wound.

Subjects enrolled to date: 599
Subjects enrolled for reporting period: 0

Progress: MAJ Milne has left the service. New chief is not going to do the study.

Detail Summary Sheet

Date: 18 Noc 88 Prot No.: 88-20		Status: Ongoing
Title: A Phase III, Randomized, Double Blind, Placebo-Controlled Study of 5-Fluorouracil, With or Without Large Doses of Sellcovorin (Leucovorin Tablets), in Measurable Metastatic Colon and Rectal Carcinoma		
Start Date:		Est Comp Date:
Principal Investigator(s) Steven Madden, M.D.		Facility: USA MEDDAC, Ft Jackson, SC
Dept/Svc: Medicine/Oncology		Associate Investigators: George P. Sartiano, M.D.
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To determine whether measurable metastatic colon and rectal carcinoma patients can benefit from oral Leucovorin tablets combined with 5-Fluorouracil chemotherapy.

Technical Approach:

Number of subjects enrolled to date: 0
Number of subjects enrolled during reporting period: 0

Progress: No patients enrolled at present time.

Detail Summary Sheet

Date: 26 Sep 88 Prot No.: 88-31		Status: Ongoing
Title: Identification of the Information New Mothers Perceive as Helpful During Early Breastfeeding		
Start Date: Aug 88		Est Comp Date:
Principal Investigator(s) Lee Ann Street, B.S.N., R.N.		Facility: MEDDAC, Ft McClellan, AL
Dept/Svc: Obstetrics		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objectives: 1) Identify the basic information mothers report as helpful to early breastfeeding. 2) Identify the basic information new mothers report they wish they had had during early breastfeeding. 3) Identify the sources of information new mothers report using during early breasfeeding.

Technical Approach: The design of this study is descriptive. Frequencies and percentages will be the reporting statistics. Subjects in this study will be restricted to primiparas 18 years of age or older, desiring to breastfeed, who have had a vaginal birth of a single infant weighing at least 5.5 pounds. Those with maternal or infant complications during the pueperium will be excluded. The sampling method will be a sample of convenience. Subjects will be identified through post-partal and nursery charts or the unit's Kardex. Subjects will be approached during their hospital stay. Informed consent and any demographic data not available from the chart will be secured at that time. Three weeks after the mother's delivery date the investigator will conduct the telephone interview.

Number of subjects enrolled to date:
Number of subjects enrolled during reporting period:

Progress: No reportable data available, local approval late FY 88.

Detail Summary Sheet

Date: 8 Nov 88 Prot No.: 78-14		Status: Ongoing
Title: Intraocular Lens Study.		
Start Date: Feb 88		Est Comp Date:
Principal Investigator(s) Eugenio F. Bird, MD, MAJ, MC		Facility: USA MEDDAC, Ft Polk, LA
Dept/Svc: Surgery/Ophthalmology		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results Continue

Study Objective: Provide data to support FDA approval for marketing intraocular devices.

Technical Approach: Surgical implant of intraocular lens.

Number of subjects enrolled to date: 39
Number of subjects enrolled for reporting period: 39

Progress: No complications.

Detail Summary Sheet

Date: 13 Oct 88	Prot No.: 78-14	Status: Ongoing

Title: Intraocular Lens Study.

Start Date: Oct 80		Est Comp Date:
Principal Investigator(s) David A. Hanks, DO, MAJ, MC		Facility: USA MEDDAC, Ft Rucker, AL
Dept/Svc: Surgery/Ophthalmology		Associate Investigators: William F. Varr, MD, CPT, MC
Key Words: Intraocular Lens Aphakia Implant Surgery Ophthalmology		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: The objective of the ongoing FDA study is to determine the safety of the intraocular lens implant in the human eye.

Technical Approach: In all primary implants during this period, the extracapsular cataract approach was used. A style 20 posterior chamber lens manufactured by Surgidev Corporation was placed in the posterior chamber. Also used were Cilco SK 21-UO, Cilco SAC-5, and 3M Style 83.

Subjects enrolled to date: 452
Subjects enrolled for reporting period: 38

Progress: 1 anterior chamber and 37 posterior chamber implants.

Detail Summary Sheet

Date: 28 Sep 88 Prot No.: 78-14 Status: Ongoing
Title: Intraocular Lens Study.

Start Date: Nov 84		Est Comp Date:
Principal Investigator(s) Mark H. Cook, MD, MAJ, MC		Facility: USA MEDDAC, Ft Stewart, GA
Dept/Svc: Surgery/Ophthalmology		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: $9000	Periodic Review Results

Study Objective: Provide data to support FDA approval for marketing intraocular devices.

Technical Approach: Surgical insertion of intraocular lens.

Number of subjects enrolled to date: 109
Number of subjects enrolled for reporting period: 60

Progress: No adverse effects thus far of any lenses implanted.

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